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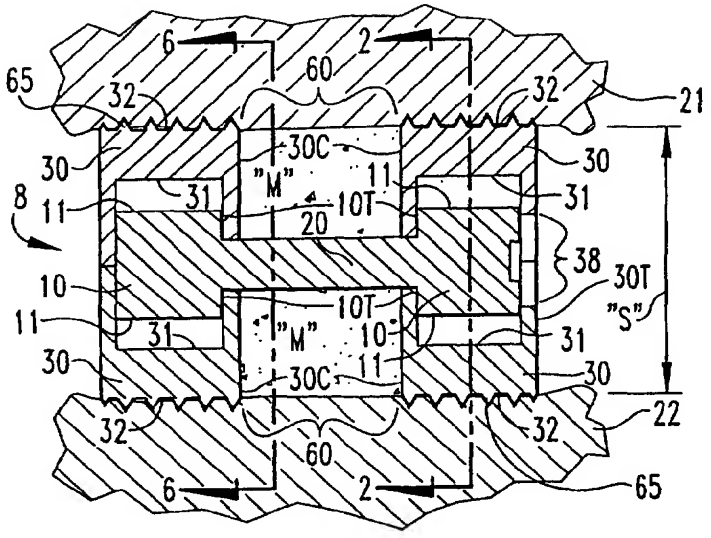
(54) Title: EXPANDABLE SPINAL FUSION DEVICE AND METHODS OF PROMOTING SPINAL FUSION



(57) Abstract: An intervertebral disc space implant includes spaced-apart bone engagement portions that define an intermediate chamber that holds bone growth inducing material into contact with adjacent vertebral bodies. The implant is expandable to establish and maintain desired intervertebral spacing during fusion. The implant includes a first member and a second member arranged to move relative to each other by action of an expansion member, the first member being engageable with the vertebral body below the disc sp.

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EXPANDABLE SPINAL FUSION DEVICE AND METHODS OF PROMOTING SPINAL FUSION

BACKGROUND OF THE INVENTION

The present invention relates to an implant device to be placed into a portion of the intervertebral space between adjacent vertebrae. Specifically, the invention concerns an expandable osteogenic fusion device that may enhance arthrodesis or fusion between adjacent vertebral bodies while also maintaining the height of the intervertebral space at the instrumented vertebral level.

In many cases, low back pain originates from damages or defects in a spinal disc between adjacent vertebral bodies. The disc can be herniated or can be affected by a variety of degenerative conditions. Frequently, pathologies affecting the spinal disc can disrupt the normal anatomical function of the disc. In some cases, this disruption is significant enough that surgical intervention is indicated.

In one such surgical treatment, the affected disc is essentially removed and the adjacent vertebral bodies are fused together. In this treatment, a discectomy procedure is conducted to remove the disc nucleus while retaining the annulus. Since the disc material has been removed, an implant must be placed within the intervertebral space to prevent the space from collapsing.

In early spinal fusion techniques, bone material, or bone osteogenic fusion devices, were simply disposed between adjacent vertebral bodies, typically at the posterior aspect of the vertebral bodies. In the early history of these bone osteogenic fusion devices, the devices were formed of cortical-cancellous bone which was generally not strong enough to support the weight of the spinal column at the instrumented level. Consequently, the spine was stabilized by way of a plate or a rod spanning the affected vertebral bodies. With this technique, once fusion occurred across the vertebral bodies and incorporated the bone osteogenic fusion device, the hardware used to maintain the stability of the spine became superfluous.

Following the successes of the early fusion techniques, focus was directed to modifying the device placed within the intervertebral space. Attention was then turned to

implants, or interbody fusion devices, that could be interposed between the adjacent vertebral bodies, maintain the stability of the disc interspace, and still permit bone fusion or arthrodesis. These interbody fusion devices have taken many forms. For example, one prevalent form is a cylindrical hollow implant or "cage". The outer wall of the cage creates an interior space within the cylindrical implant that is filled with, for example, bone chips or other bone growth-inducing material. In recent years compounds known as bone morphogenetic proteins (BMPs) have become the preferred bone growth inducing material. In some cases, the cylindrical implants included a threaded exterior to permit threaded insertion into a tapped bore formed in portions of the adjacent vertebral bodies. Alternatively, some fusion implants have been designed to be impacted into the intervertebral space. Yet another class of fusion implants can be placed in between adjacent vertebral bodies and then expanded to contact the opposing surfaces of the vertebral bodies.

Experience with some interbody fusion devices has demonstrated the efficacy of some such implants in yielding a solid bone fusion. Variations in the design of the implants have accounted for improvements in stabilizing the motion segment while fusion occurs. Nevertheless, with some of the interbody fusion devices, there remains difficulty in achieving a complete fusion, at least without the aid of some additional stabilizing device, such as a rod or plate. Moreover, some of the devices are not structurally strong enough to support some loads and bending moments applied at certain levels of the spine.

Further difficulty has been encountered when a surgeon, desiring to avoid removal of the spinal facet joints laterally, uses an undersized interbody fusion cage in a posterior lumbar interbody fusion procedure (PLIF). Use of undersized devices results in sub-optimal contact with the endplates of adjacent vertebral bodies and consequent sub-optimal bone formation inside the device, and can lead to pseudoarthrosis. Additionally, undersized devices may not provide adequate disc space distraction and nerve root decompression. Due to the high degree of anatomical and physiological variation encountered in all surgery, efforts to avoid utilization of a posteriorly undersized implant can require the availability of numerous devices of different dimensions, and increase the time required to carry out the surgical procedure, thus increasing the cost and risk associated with the procedure. Some prior efforts to address this difficulty through use of

expandable devices have utilized designs involving numerous parts, or designs that apply excessive stress force to the device, resulting in device strain. These design approaches increase the risk of mechanical failure. Also, they may occlude the space between vertebral body endplates, inhibiting fusion from adequately occurring.

Even with devices that do not have the aforementioned difficulties, still other undesirable characteristics exist. Studies have suggested that the interbody fusion implant devices, especially those implants of the "cage" design, lead to stress-shielding of bone material within the cage. It is well known that bone growth is enhanced by stressing or loading the bone material. The stress-shielding phenomenon relieves some or all of the load applied to the bone material to be fused, which can greatly increase the time for complete bone fusion, or disturb the quality and density of the ultimately formed fusion mass. In some instances, stress-shielding can cause the bone chips or fusion mass contained within the fusion cage to resorb or evolve into fibrous tissue rather than into a bony fusion mass.

A further difficulty encountered with many fusion implants is that the material of the implant is not radiolucent. Most fusion cages are formed of metal, such as stainless steel, titanium or porous tantalum. The metal of the cage shows up prominently in any radiograph (x-ray) or computer tomography (CT) scan. Since "cage" type fusion devices surround and contain the bone graft material housed within a metal cage, the developing fusion mass within the cage cannot be seen under traditional radiographic visualizing techniques, and can be seen in CT scans only with the assistance of image scatter techniques. Thus, the spinal surgeon does not have adequate means to determine the progress of the fusion, and in some cases cannot ascertain whether the fusion was complete and successful.

Thus, the field of spinal fusion lacks a suitable intervertebral fusion device that can be made small enough to facilitate insertion in the intervertebral space and support bone growth material within the intervertebral space and expand to maintain the normal height of the disc space. Further, current spinal fusion devices do not sufficiently reduce the risk of stress-shielding the fusion mass and do not enable visualization of the fusion mass as the arthrodesis progresses. So, there remains a need for improvements in osteogenic

fusion device technology, particularly devices that provide expandable characteristics. The present invention addresses this need in a novel and non-obvious fashion.

SUMMARY OF THE INVENTION

To address the current needs with respect to interbody fusion devices, the present invention contemplates an expandable osteogenic fusion device for promoting osteogenic fusion in an intervertebral disc space between adjacent vertebral bodies. The device includes a first configuration to enable placement with minimal surgical exposure for access to the space and a second configuration that expands in the space to provide proper disc space distraction. Further, the expanded device enables retention of an optimum amount of bone growth fusion material and placement of the bone growth inducing material into contact with adjacent bone.

In one embodiment, the expandable implant includes a cam. The cam is in contact with an interior surface of a first member. The first member contacts a portion of one of the adjacent vertebral bodies. The cam is also in contact with an interior surface of a second member. The second member contacts a portion of the other of the adjacent vertebral bodies. The implant can be expanded by simply turning the cam, and thereby without the cam undergoing substantial translational displacement, to cause one of the first member and the second member to move slightly away from the other for the desired expansion.

Another embodiment of the present invention also contemplates an expandable implant for promoting osteogenic fusion in an intervertebral disc space between adjacent vertebral bodies. This embodiment includes a first member for contacting a portion of one of the adjacent vertebral bodies and a second member for contacting a portion of the other of the adjacent vertebral bodies. The first member has a bore defined therein. The bore is threaded along substantially its entire length. This embodiment further includes a screw having a threaded region and further having a region of gear teeth. The threaded region of the screw is at least partially threaded into the bore. The screw contacts the second member in a manner permitting the screw to rotate. This embodiment further includes an axle having a threaded region. The threaded region of the axle engages the gear teeth of

the screw to function as a worm and pinion gear assembly operable to produce the desired expansion.

Yet another embodiment of the present invention contemplates an expandable implant for promoting osteogenic fusion in an intervertebral disc space between adjacent vertebral bodies. This embodiment includes a first member for contacting one of the adjacent vertebral bodies and a second member for contacting the other of the adjacent vertebral bodies. This embodiment further includes a rack having a plurality of gear teeth. The rack is in contact with one of the first member and the second member. An axle having a pinion gear is further included. The axle is coupled to the other of the first member and the second member in a manner that allows the axle to rotate. The pinion gear of the axle contacts at least one of the plurality of gear teeth of the rack to form a rack and pinion operable for the expansion.

Still another embodiment of the present invention contemplates an expandable implant for promoting osteogenic fusion in an intervertebral disc space between adjacent vertebral bodies, and includes first and second initially abutting each other. The first member is substantially adjacent to one of the vertebral bodies. The second member is substantially adjacent to the other vertebral body. A spring for expanding the implant from a first configuration to a second configuration is also included in this embodiment. The spring is compressed when the implant is in the first configuration. One portion of the spring is in physical contact with the first member and another portion of the spring is in physical contact with the second member.

In still another embodiment of the present invention an expandable implant for promoting osteogenic fusion in an intervertebral disc space between adjacent vertebral bodies includes first and second initially abutting each other. The first member is substantially adjacent to one of the vertebral bodies. The second member is substantially adjacent to the other vertebral body. A manufactured body for expanding the implant from a first configuration to a second configuration is also included. The manufactured body is capable of assuming a first state and a second state. A first portion of the manufactured body is in physical contact with the first member and a second portion of the manufactured body is in physical contact with the second member to spread the first and second after insertion into the intervertebral space.

An additional set of embodiments much like those summarized above is provided with a rectangular external cross-sectional shape instead of the circular external cross-sectional shape.

An additional embodiment of the present invention contemplates a method of promoting osteogenic fusion of adjacent vertebral bodies. The method includes the step of providing an expandable implant that defines a void intermediate a part of the implant and one of the vertebral bodies when the implant is substantially adjacent to the vertebral body. The step of positioning the expandable implant substantially intermediate a first vertebral body and a second vertebral body is further included in the present embodiment of the invention. Still further included is the step of expanding the implant while maintaining the void.

In the various embodiments of the present invention, the expandable implant maintains intervertebral disc space between adjacent vertebral bodies while providing a void intermediate the vertebral bodies where the bone growth inducing material may be packed, thereby minimizing the above-mentioned stress-shielding of bone material while enabling radiographic visualization of the developing fusion mass.

Therefore, embodiments of the present invention provide an improved expandable osteogenic fusion device. Numerous advantages and additional aspects of the present invention will be apparent from the description of the preferred embodiments and drawings that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side sectional view of a first embodiment of the present invention at line 1-1 in FIG. 2 and viewed in the direction of the arrows.

FIG. 2 is an end sectional view of the embodiment of FIG. 1 taken along line 2-2 in FIG. 1 and showing the implant in a non-expanded position.

FIG. 3 is an end view of the embodiment of FIG. 1 showing the implant in a non-expanded position.

FIG. 4 is an end sectional view of the embodiment of FIG. 1 taken along line 2-2 in FIG. 1 and showing the implant in an expanded position.

FIG. 5 is an end view of the embodiment of FIG. 1 showing the implant in an expanded position.

FIG. 6 is a view along the longitudinal axis of the embodiment of FIG. 1 taken at line 6-6 showing the implant in an non-expanded position.

FIG. 7 is a view like FIG. 6 but showing the implant in an expanded position.

FIG. 8 is a side partial sectional view of a second embodiment of the present invention.

FIG. 9 is a side view of the second embodiment of the present invention.

FIG. 10 is an end partial sectional view of the embodiment of FIG. 8 taken along line 10-10 showing the implant in a non-expanded position.

FIG. 11 is an end partial sectional view of the embodiment of FIG. 8, similar to Fig. 10, showing the implant in an expanded position.

FIG. 12 is an end view of the embodiment of FIG. 8 showing the implant in a non-expanded position.

FIG. 13 is end view of the second embodiment of the present invention showing the implant in an expanded position.

FIG. 14 is a perspective view of a locking cap.

FIG. 15 is a side partial sectional view of a third embodiment of the present invention.

FIG. 16 is an end sectional view of the embodiment of FIG. 15 taken along line 16-16 showing the implant in an non-expanded position.

FIG. 17 is a detailed view of a portion of the third embodiment showing a ratcheting mechanism.

FIG. 18 is an end sectional view of a variation similar to Fig. 16, showing the implant in an non-expanded position and including springs.

FIG. 19 is an end sectional view of a variation showing an implant in non-expanded position with only springs.

FIG. 20 is an end sectional view of a second variation of a fourth embodiment of the present invention taken along line 20-20 of FIG. 24 showing the implant in a non-expanded position.

FIG. 21 is an end sectional view of the second variation of the fourth embodiment of the present invention showing the implant in an expanded position.

FIG. 22 is an end view of the second variation of the fourth embodiment of the present invention showing the implant in a non-expanded position.

FIG. 23 is an end view of the second variation of the fourth embodiment of the present invention showing the implant in an expanded position.

FIG. 24 is a side sectional view of the second variation of the fourth embodiment of the present invention showing the implant in a non-expanded position.

FIG. 25 is an end sectional view of a third variation of the fourth embodiment of the present invention showing the implant in a non-expanded position.

FIGS. 26 through 50 illustrate various embodiments generally corresponding to those shown in FIGS. 1 through 25 but wherein the configuration of the implants as viewed along the implant axis is generally rectangular, rather than circular.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Such alterations and further modifications in the illustrated device and such further applications of the principles of the invention as illustrated therein as would normally occur to one skilled in the art to which the invention relates are contemplated as within the scope of the invention.

The drawings show various embodiments of an implant for insertion into the intervertebral space between adjacent vertebrae and include first and second end members for engaging respective ones of the adjacent vertebrae, and an expansion member for changing the implant from a first state suitable for insertion into the intervertebral space between the distracted vertebrae, to a second state suitable for maintaining a predetermined spacing between the adjacent vertebrae. The expansion member may include any system or mechanism for changing the spacing between upper and lower portions of the first end member and upper and lower portions of the second end member in a direction substantially aligned with the longitudinal axis of the spine at the site of the

adjacent vertebra, while maintaining substantially the same position in an axis perpendicular to the longitudinal axis of the spine. Additionally, the first and second end members have lateral portions that are spaced apart and define an intermediate chamber between the adjacent vertebrae suitable for retaining a bone growth-inducing material. The expanded end members can handle loads imposed while maintaining the predetermined spacing during fusion. By communicating with the adjacent vertebrae, the intermediate chamber allows the transmission of loads from one vertebrae to the adjacent vertebrae through the bone growth inducing material, thereby facilitating fusion. Thus, the implant maintains the predetermined spacing between the adjacent vertebrae while promoting fusion of the adjacent vertebrae through the bone growth inducing material.

In accordance with a first embodiment of the present invention, an expandable osteogenic fusion implant 8, depicted in FIGS. 1-7, has a cam-action expansion member. Implant 8 includes cams 10 connected at opposite ends of a connecting member 20, and two end members 30, respectively, enclosing each cam. Cams 10 have an outer surface that contacts a first portion of the inner surface of each of the ends 10 when the implant is not expanded, but when rotated as in FIG. 4, the cams 10 contact a second portion of each of the end members 30. The end members 30 further include exterior surfaces 32 that contact the endplates of the vertebral bodies 21 and 22, respectively, above and below the disc space "S" of FIG. 1 when the implant is in an expanded configuration. Exterior surfaces 32 may include a bone engaging configuration 65, such as threads or ridges to promote a secure positioning of the implant or to enable insertion of the implant. The implant transforms from the non-expanded configuration to the expanded configuration by, for example, a rotation of the cams 10 about the longitudinal axis of connecting member 20. As the cams 10 rotate, they exert forces on surfaces 31 of end members 30 that cause end members 30 to move apart from one another. By selecting the size and configuration of the cooperating surfaces of the cams 10 and end members 30, the expansion of the implant can be controlled to provide desired distraction of adjacent vertebral bodies and nerve root decompression. Expansion distances of one to eight millimeters, depending on the size and shape of the implant, such as one to three for small, one to six for medium, and one to eight for large, are examples. It will be appreciated by one of ordinary skill in the art that cams 10, while illustrated as largely identical in FIG. 1,

may have different shapes, sizes and configurations from one another. Similarly, one of ordinary skill in the art will recognize that end members 30 while illustrated as substantially identical in FIG. 1, may also have different shapes, sizes and configurations from one another.

In this embodiment, the cams 10 are positioned and secured at opposite ends of the elongate connecting member 20 that extends intermediate the cams 10. Member 20 and cams 10 may be one integral homogeneous piece of material, or may be separate pieces joined together. Some examples of techniques for connecting member 20 and cams 10 include staking, threading, screwing, bolting, or welding. Additionally, connecting member 20 may be configured to join cams to along their axes of rotation, or may be configured to connect the cams at any position that transmits the rotation of one cam to the other cam. Additionally, one or more cams 10 may be positioned at any point along central member 20.

Variations of the embodiment described above and shown in FIGS. 1-7 are within the scope of the invention. For example, one of cams 10 is shown in FIGS. 2 and 4 as having a substantially elliptical cross sectional shape, however, it is contemplated that cams 10 could have almost any cross sectional shape that would provide a greater distance along a first axis than along a second axis while permitting the cam to be intentionally turned by the surgeon. For instance, cams 10 could have an oval cross section or a cross section that is generally rectangular with rounded corners. It should be understood also that interior surfaces 31 can also assume a variety of shapes cooperating with the shape of the cams 10. Regardless of the specific cross sectional shape of the cams 10 and the shape of interior surfaces 31, implant 8 may include a retainer mechanism to secure the position of cams 10 and thereby maintain the implant in the expanded position. For example, interior surfaces 31 may be adapted to hold cams 10 in a fixed position when the implant has been transformed to the expanded position. Referring to FIGS. 2 and 4, for example, retainer mechanism includes cavities 33 formed along interior surfaces 31 that are not occupied in the non-expanded position (see FIG. 2), but that are occupied by the cams 10 in the expanded position (see FIG. 4). For example, cavities 33 include surfaces having a radius of curvature less than the radius of curvature of the corresponding portion of the surface of the cam. As such, a predetermined difference in the radius of curvatures

requires a predetermined rotational force to move the cam out of the cavity. In other embodiments, the retainer mechanism may include notches, tabs and other similar structures to secure the cams to hold the implant in the expanded position. Thus, in the expanded position, the portions of interior surfaces 31 that define the cavities 33 in the non-expanded position contact the cams 10 and resist movement of the cams 10 out of the expanded position.

It will further be understood that exterior surfaces 32, while in one embodiment may be substantially semi-circular in shape, as shown in FIGS. 2-7, can be provided in a variety of other shapes. Moreover, it is contemplated that at least portions of surfaces 32 may also include a variety of adaptations designed to secure them to the surface of a vertebral body. The surfaces 32 may include bumps, ridges, threads, spikes, grooves, slots or other features to ensure that the surfaces 32 securely contact the vertebral body and do not slip out of position.

Additionally, each of end members 30 may include a truncated outer wall 30T (FIG. 1). Truncated wall 30T defines an access gap 38 that provides access to one of the cams 10 from the exterior of implant 8. Cam 10 may further include a tool receptacle 21, shown in FIGS. 3 and 5. Tool receptacle 21 can be provided in a wide variety of shapes, including but not limited to a Phillips head shape, a flathead shape, a star shape, a hex-wrench shape, and a square shape. The receptacle 21 facilitates the expansion of the implant by receiving a tool (not shown) that may be turned to cause the rotation of the cams 10.

Additionally, implant 8 may further include an assembly connector device or mechanism to hold end members 30 together with the cams 10 and thus prevent the components of the implant from becoming completely separated during handling and insertion into the intervertebral space. The assembly connector may include any structure that maintains a connection between the end members 30 and the cams 10. One example is a fine wire encircling the ends and which may be permanent or biodegradable or absorbable. If permanent, it would not be strong enough to resist the expansion feature of the invention. In another connector example shown in FIGS. 6-7, implant 8 includes pins 14 projecting through slots 37 in a wall 30C of each of the respective top and bottom end members 30. The pins are fixed in shoulders 10T of each of the cams 10. The slots 37

receive the pins 14 and the pins thus retain the end members 30 about the cams 10. The slots 37 are configured to form a path defined by the pins 14 as the cams 10 rotate. If desired, an assembly connector device or mechanism may take the form of any shaped protrusion and corresponding slot, or any other device or mechanism that prevents the cams 10 and end members 30 from becoming completely separated during insertion or during handling prior to insertion of the implant.

Additionally, referring to FIG. 1, implant 8 includes internal chamber ends 60, defined by walls 30c of end members 30, elongate connecting member 20, and by adjacent vertebral bodies 21 and 22 when the implant is inserted between the adjacent vertebral bodies. Chamber 60 may be filled with a material that promotes bone growth. A variety of such bone growth promoting materials may be used. For example, chamber 60 may be packed with a material composition including an osteoinductive factor such as bone morphogenetic protein (BMP) or LIM mineralization protein (LMP). For example, BPM-1, BMP-2 or BMP-11 might be used. Demineralized bone matrix (DBM), bone in particulate form such as chips or powder, might also be used. A conductive or scaffolding material might also be used. Examples are bone, or a bioceramic such as biocompatible calcium phosphate ceramics. Examples of those include biphasic calcium phospate, tricalcium phosphate, and preferably a hydroxyapatite paste material such as described in ETEX, Corp. U.S. Patents Nos. 6,331,312, 6,214,368, 6,117,456, and 6,027,742. Numerous methods
could be used to fill chamber 60. For example a paste could be packed within chamber 60. Another alternative is to spool a collagen sheet coated with BMP around the connecting member 20. The sheet may have a width substantially equivalent to the width of chamber 60 defined by end members 30. Yet another possibility is to inject bone growth promoting material through the gaps 61 (FIG. 5) when the implant is in an expanded position. Also, if two implants according to this embodiment are positioned side-by-side within disc space "S", then space is provided for inserting bone growth promoting materials in chamber 60.

In accordance with a second embodiment of the present invention, shown in FIGS. 8-14, an expandable osteogenic fusion implant 200 includes a screw-type expansion member. Implant 200 includes end members with upper end portions 230a and lower end portions 230b, each having one or more threaded bores 231 (FIG. 11). In one version of

this second embodiment, shown in FIG. 8, elongate central members 233a and 233b extend between and connect the upper end portions 230a and the lower end portions 230b, respectively, of the end members. Alternatively, in another embodiment, and referring to FIG. 9, implant 210 includes only one elongate central member 233 extending between either the upper end portions 230U or the lower end portions 230L. In either case, the elongate central members 230a, b, or member 233, if only one is to be used, may be attached to the upper or lower end portions. Some examples of suitable attachment methods are welding, screwing or bolting. Alternatively, end portions 230a and 230b and the elongate central member portions 233a, b and member 233 may be manufactured as one piece. The implant 200 further includes screws 250, each having screw threads 251a and 251b and gear teeth 252 (FIGS. 10, 11 and 13). Referring to FIGS. 8 and 10, there are four of these screws although more or fewer screws may be utilized. The implant 200 also includes central axle 220 having central axle threads 221 at each end (FIG. 8) which act as a gear worm engaging the gear teeth 252 to turn the screws and expand the implant.

Screw threads 251a at one end of screws 250 are left hand threaded, and screw threads 251b at the other end of screws 250 are right hand threaded. Thus rotating a screw 250 about its longitudinal axis in a first direction will cause the screw 250 to thread itself into threaded bore 231 of upper end member 230a and into threaded bore 231 of lower end member 230b. Rotating a screw 250 in a second direction opposite the first will cause screw 250 to thread itself out of threaded bore 231 of upper end member 230a and thread itself out of threaded bore 231 of lower end member 230b. Alternately, each screw and bore may only be threaded at one end. In another embodiment, the upper and lower end portions are not connected by a central portion, and the screws and bores at opposite ends of the implant have differently pitched threads, thereby expanding each end at a different rate to impart a predetermined curvature to the adjacent vertebrae.

Central axle 220 is positioned between upper end 230a and lower end 230b. Central axle 220 is further positioned so that central axle threads 221 contact gear teeth 252 of each of the screws 250. This configuration forms a plurality of worm gears. When central axle 220 is rotated about its longitudinal axis, central axle threads 221 successively engage gear teeth 252 of the screws 250 thus causing the screws 250 to rotate about their longitudinal axes. Due to the fact that the screws 250 on each end of implant 200 are

positioned on opposite sides of the central axle 220, turning the central axle 220 will cause the screws 250 to turn in opposite directions as the central axle threads 221 engage the gear teeth 252. Thus, the rotation of central axle 220 causes the expansion of the implant by rotating the screws 250.

It should be understood that screws 250 might include only one of threaded portions 251a and 251b. In such case, a smooth shank portion (not shown) may be substituted for the omitted one of threaded portions 251a and 251b. Also, one of the upper end 230a and lower end 230b may have bores 231 that are unthreaded and that receive the smooth shank portions. While rotation of the screws will cause displacement of the end in which they are threaded, such as upper end 230a, the smooth shank portions of the screws will rotate freely in the unthreaded bores, such as in lower end 230b, and that end will not be displaced. The resulting expansion of implant 200 is shown in FIG. 13.

Additionally, implant 200 may include tool receptacle 222 at one end of central axle 200 for receiving a tool to rotate the central axle and expand or contract the implant. Tool receptacle 222 may have a variety of shapes including but not limited to a hexagonal wrench shape, a star shape, a Phillips head shape, a flathead shape, and a square shape. The implant 200 may further include locking cap 260 (FIG. 14) that connects to the end of the implant having tool receptacle 222 to prevent rotation of central axle 222. In one embodiment, locking cap 260 has an inside face 260a having a post 262 adapted to fit into turning tool receptacle 222. Locking cap 260 further includes screw holes 261 to receive screws 230s inserted from the outside face and screwed into screw holes 230c and 230d after the desired expansion has been established. Thus, locking cap 260 is capable of preventing central axle 220 from rotating about its longitudinal axis by engaging post 262 with turning tool receptacle 222 and by further engaging the engaging screws with upper end member 230a and lower end member 230b by passing them through screw holes 261 and threading them into upper end member 230a and lower end member 230b. Other devices, such as pins, rivets or posts could be substituted for screws.

In operation, since the central axle 220 drives screws 250 on opposite sides (i.e. the left and right sides as viewed in FIGS. 10 and 11) of central axle 220, the screws are threaded into threaded bores 231 of common upper end member 230a in opposite directions. Thus the screws 250 on opposite sides of the central axle 220 would turn in

opposite directions. So when axle 220 is rotated, the screws are simultaneously either threading into or out of the bores 231, depending on the direction of shaft rotation. So they simultaneously move the member 230a in the same direction relative to the screws. As stated above, the threads on opposite ends of each screw may be oppositely threaded. So screws 250 are threaded into threaded bores 231 of the common lower end member 230b in the direction opposite that in the common upper end member. Thus both ends of the screws 250 accomplish the same movement relative to the upper and lower end , either threading into or out of the bores 231.

In accordance with a third embodiment, referring to FIGS. 15-18, an expandable osteogenic fusion implant 300 includes a rack-and-pinion type expansion member. implant 300 includes upper end 330a and lower end 330b, having corresponding bores 331. Elongate central portions 333a and 333b extend between and connect the respective upper end portions 330a and the lower end portions 330b. Alternatively, only one elongate central member 333 may be included extending between either the upper end portions 330a or the lower end portions 330b. In either case, the elongate central member may be permanently or removably attached to the end portions 330a and/or 330b, such as by welding, screwing or bolting. Alternatively, the end portions 330a and 330b and the elongate member 333 may be formed as one piece. The implant 300 further includes gear racks 350, having rack teeth 351, disposed within each bore 331. The implant 300 also includes central axle 320 having central axle gear teeth 321 corresponding with rack teeth 351. Gear teeth 321 may be disposed directly on central axle 320 or, alternatively, may be disposed on a separate pinion gear that is adapted to fit around the axle.

In operation, rack teeth 351 of one rack 350 contact the gear teeth 321 on one side of the central axle 320. Rack teeth 351 of another rack 350 contact the gear teeth 321 on the other side of the central axle 320. This configuration forms a plurality of racks and pinions. Central axle 320 is positioned intermediate upper end 330a and lower end 330b. When central axle 320 is rotated about its longitudinal axis, central gear teeth 321 successively engage teeth 351 of the racks 350 thus cause the racks 350 to be displaced. Due to the fact that the racks 350 are positioned on opposite sides of the central axle 320, rotation of the central axle 320 will cause the racks 350 to be displaced in opposite directions when the gear teeth 321 engage the respective rack teeth 351. Thus when

adjacent racks 350 are displaced, one of them will come into contact with the end of bore 331 in upper end member 330a and the other will come into contact with the end of bore 331 in lower end member 330b. When the racks contact bore ends in 330a and 330b, they will exert forces upon them. The force exerted upon the upper end member 330a will be in a first direction and the force exerted upon the lower end member 330b will be in a second opposite direction. Due to the opposing nature of these forces, rotating central axle 320 will cause the expansion of the implant 300. In another embodiment similar to implant 300, referring to FIG. 18, an implant 300 may further include springs 370, disposed in bores 331. Springs 370 contact racks 350 and bores 331 and exert a force upon racks 350 to assist in the expansion of the implant. Springs could be added to implants 200 and 210 (FIGS. 8-13), if desired.

Further, referring to FIG. 16, central axle 320 includes a tool receptacle 322 at one end. Tool socket 322 may be provided in a variety of shapes including, but not limited to a hexagonal wrench shape, a star shape, a Phillips head shape, a flathead shape, and a square shape. Rotation of the central axle 320 may be accomplished by inserting the tool into the tool receptacle 322 and rotating the tool. A T-handled Allen wrench is one example of a tool. The implant may further include a locking cap 260, as shown in FIG. 14 and functioning as described above, including a post 262 adapted to fit into turning tool receptacle 322.

Additionally, implant 300 may include ratcheting mechanisms 389 (FIG. 17) disposed in recess 380 formed in bores 331 of upper end 330a and lower end 330b. Suitable ratcheting mechanisms 389 include, for example, axles 390 and engaging bodies 391. Recesses 380 allow the engaging bodies 391 to pivot in a first direction, but to prevent pivoting past a certain position in a second opposite direction. Engaging bodies 391 are shaped to fit between and engage the rack teeth 351 (FIG. 17). When racks 350 are displaced in a first direction, rack teeth 351 exert a force on engaging bodies 391 and cause them to pivot in a first direction and move partially into recesses 380, and then the bodies pivot back into the next successive space between the teeth as the rack is further displaced. In their original position, the bodies 391 contact one side of recesses 380, thereby preventing pivoting of the bodies in that direction. When engaging bodies 391 can no longer pivot and are positioned intermediate the rack teeth 351, the rack 350 is

prevented from moving further in the second direction. In this manner, the implant may be ratcheted open. Additionally, a biasing member such as a spring may be used to force the body in the non-pivoting position. Other ratcheting mechanisms could be substituted for ratcheting mechanisms 389. For example, mechanisms that do not pivot, but flex, could be used.

In another embodiment of the invention, variations include biasing-type expansion members. Referring specifically to FIGS. 20-24, implant 400 includes upper and lower end 430a and 430b having cavities 451a and 451b. Elongate central member 433 extends between lower ends 430b. Alternatively, elongate central member 433 may extend between the upper ends 430a. In another alternative, an upper and a lower elongate central member may extend, respectively, between the upper end member 430a and the lower end member 430b. In any case, the elongate central member 433 may be fixably or removably attached to the end 430a and/or 430b, such as welding, screwing or bolting. Alternatively, the end and the elongate member may be formed as one piece.

The expandable osteogenic fusion implant 400 further includes bodies 450 having upper surfaces 451a and lower surfaces 451b abutting the ends of the bores in each end 430a and 430b. The bodies 450 are made of a material that is capable of assuming multiple shapes. One of ordinary skill in the art will appreciate that a wide variety of materials and structures may be used to construct bodies 450. For example, bodies 450 may be made of a shape memory alloy. In this case the bodies 450 could be designed to change shape or, alternatively, to expand when subjected to specific environmental conditions, such as heating or cooling the implant. The implant 400 of FIGS. 20-24 have a single body in each end member, while FIG. 25 shows how two bodies could be used in an end member. Phase change expansion of a few millimeters may be achieved.

Bodies 450 may be compressible bodies. Some examples are a polymer or other elastomer or a spring. Suitable examples of a spring includes coil springs, leaf springs, springs made of shape memory alloy and any other spring-like member. In these cases, an external force applied to the bodies (as by a tool) causes the bodies 450 to assume a compressed state, and the bodies 450 could then be held in that state until the implant is inserted into the desired surgical position. At that time the force compressing the bodies 450 could be released or reduced and the bodies could reassume a relaxed state, thereby

expanding the implant by a predetermined amount. The variation 420 shown in FIG. 19 is an example using coil springs 450c as the compressible body.

In the FIG. 25 variation, implant 410 may include multiple bodies 450 of either a phase change type of material or a compressible body disposed within the ends 410a and 410b to cause expansion of the implant.

It is of note that, when viewed along their longitudinal axes, the implants described above are circular. Their ends have a short cylindrical shape.

Referring now to FIGS. 26-50, the reference numerals used for implant components having functions similar to or identical to those described above with reference to FIGS. 1-25, are as used in FIGS. 1-25 but with the letter R in front of them. These implants, when viewed along their longitudinal axes, are rectangular. Their ends have the shape of a short parallelepiped.

A set of barbs 510 is provided on each of the end members R30 so that, after pushing or impacting the implant in the direction of arrow 520 into the intervertebral space, there will be added resistance to movement in the opposite direction out of the space. These barbs can be provided on the top surface and bottom surface such as shown at the top and bottom in FIGS. 26, 27, 29, 31, and 32, extending entirely across the implant. They can also be provided in other shapes, numbers and in multiples across one row with various spacings, as desired. They are not shown in FIGS. 28 and 30 in order to avoid congestion in the illustration where the intent is to show, in FIG. 28, slight spacing between the vertebral endplates and the top and bottom of the end members R30, and to show in FIG. 30 the closure of the space between the end members and the vertebral plates as the implant has been expanded. Barbs are also shown on the top and bottom faces of the end members of variation R210 in FIG. 34. As indicated above, barbs can be omitted from one or both end members of these and the other embodiments, if desired. This can be observed in FIGS. 33, 35-38, 40, 41, and 43-50, for example.

In the various embodiments of FIGS. 1-25, the end can be externally screw threaded as shown at 65 for example in FIG. 1, so that they can be screwed into the intervertebral disc space, if desired. Even without threads, they can be simply pushed or impacted into the space. The embodiments of FIGS. 26-50 can be pushed or impacted into the space regardless of whether they are provided without barbs or with barbs such as

shown in FIG. 26 for additional anchorage. But due to the fact that the implants are expandable, they can be made small enough that they can be inserted into the intervertebral space without impacting them and then they can be expanded to maintain the desired spacing of the plates of the adjacent vertebral bodies, according to the present invention.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that all changes and modifications to the described embodiments that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A spinal implant positionable in an intervertebral disc space between adjacent vertebral bodies in a spine and comprising:

a first cam;

a first member for contacting an endplate of one of the adjacent vertebral bodies, the first member having a first surface, at least a portion of the first surface being in physical contact with a portion of the first cam;

a second member for contacting an endplate of the other of the adjacent vertebral bodies, the second member having a second surface, at least a portion of the second surface being in physical contact with a portion of the first cam; and

wherein the first cam is capable of causing one of the first member and the second member to move apart from the other of the first and second member without the first cam undergoing substantial translational displacement.

2. The implant of claim 1 and further comprising:

an assembly connecting mechanism.

3. The implant of claim 2 wherein:

the assembly connecting mechanism includes a first object protruding from the first cam; and

a slot in the first member shaped to receive the first object.

4. The implant of claim 1 further comprising:

a second cam;

a third member for contacting the endplate of the one of the adjacent vertebral bodies, the third member having a third surface, at least a portion of the third surface being in physical contact with a portion of the second cam;

a fourth member for contacting the endplate of the other of the adjacent vertebral bodies, the fourth member having a fourth surface, at least a portion of the fourth surface being in physical contact with a portion of the second cam;

an elongate member extending intermediate the first cam and the second cam, the elongate member having a first end region attached to one of the first cam and the second cam and a second end region attached to the other of the first cam and the second cam.

5. The implant of claim 4 wherein the first member and the second member are spaced apart from the third member and the fourth member thereby defining walls for an intermediate chamber between and communicable with the endplates of both of the adjacent vertebral bodies.

6. The implant of claim 5 further comprising an osteogenic fusion promoting material disposed between said walls for engagement with the endplates of the adjacent vertebral bodies.

7. The implant of claim 6 wherein the osteogenic fusion promoting material is selected from the group consisting of BMP, LMP, and DBM.

8. An expandable spinal implant positionable in an intervertebral disc space between adjacent vertebral bodies in a spine and comprising:

a first member for contacting an endplate of one of the adjacent vertebral bodies, the first member defining a first bore, the first bore having a first threaded bore portion;

a second member for contacting an endplate of the other of the adjacent vertebral bodies;

a screw having a first threaded screw portion and a gear tooth screw portion, the first threaded screw portion being at least partially threaded into the first bore, the screw contacting the second member in a manner permitting the screw to rotate; and

an axle having a threaded axle portion, the threaded axle portion contacting the gear tooth screw portion such that rotation of the axle moves the first and second members

from a first relative spacing to a second relative spacing, to simultaneously expand the implant in the intervertebral space and against the endplates.

9. The implant of claim 8 and further comprising:

a third member for contacting the endplate of the one of the adjacent vertebral bodies, the third member having a bore;

a fourth member for contacting the endplate of the other of the adjacent vertebral bodies;

a second screw having a threaded screw portion and a gear tooth screw portion, the threaded screw portion of the second screw being at least partially threaded into the bore of the third member, and the second screw contacting the fourth member in a manner permitting the second screw to rotate;

the first member and the second member being spaced apart from the third member and the fourth member, respectively, for defining in the intervertebral disc space between the adjacent vertebral bodies, walls of an intermediate chamber in communication with said endplates of both of the adjacent vertebral bodies.

10. The implant of claim 9 and further comprising:

a bone growth inducing material disposed in the space between the first and third member and in the space between the second and fourth member for communication through the chamber with the said endplates of both adjacent vertebral bodies.

11. The implant of claim 8 further comprising a locking cap having a peripheral protruding element capable of engaging the axle and one of the first member and the second member to prevent the axle from rotating.

12. The implant of claim 8 wherein:

the second member defines a second bore;

the screw is partially disposed within said second bore.

13. The implant of claim 12 wherein:

the second bore has a second threaded bore portion; and

the screw has a second threaded screw portion, the second threaded screw portion being at least partially threaded into the second bore.

14. The implant of claim 13 wherein:

the screw is one of a plurality of screws having threaded screw portions and gear tooth portions;

the first bore is one of a first plurality of bores defined by the first member;

the second bore is one of a second plurality of bores defined by the second member;

each of the screws has its first threaded screw portion at least partially threaded into one of the first plurality of bores, and each of the screws has its second threaded screw portion at least partially threaded into one of the second plurality of bores;

the threaded axle region contacts the gear tooth portion of each of the screws.

15. An expandable spinal implant positionable in an intervertebral disc space between adjacent vertebral bodies comprising:

a first member for contacting an endplate of one of the adjacent vertebral bodies;

a second member for contacting an endplate of the other of the adjacent vertebral bodies;

a rack having a plurality of gear teeth, the rack contacting one of the first member and the second member;

an axle having a pinion gear, the axle contacting the other of the first member and the second member in a manner permitting the axle to rotate, the pinion gear contacting at least one of the plurality of gear teeth of the rack, such that rotation of the axle moves the first and second members from a first spacing of the first member relative to the second member, to a second spacing of the first member relative to the second member to expand the members against the endplates of the adjacent vertebral bodies.

16. The implant of claim 15 wherein one of the first member and the second member includes a ratcheting mechanism contacting at least one of the plurality of gear teeth of the rack, the ratcheting mechanism having a first position permitting displacement of the rack in a first direction and a second position preventing displacement of the rack past a certain distance in a second direction.

17. The implant of claim 15 wherein the rack is partially disposed within a bore extending between the first member and the second member.

18. The implant of claim 15 wherein:

the rack is one of a plurality of racks;

the pinion gear contacts at least one of the plurality of gear teeth of each of the racks.

19. The implant of claim 18 wherein a first one of the racks exerts a first force on one of the first member and the second member when the rack is displaced, and wherein a second one of the racks exerts a second force on the other of the first member and the second member when the second rack is displaced.

20. The implant of claim 15 and further comprising:

a third member for contacting the endplate of the one of the adjacent vertebral bodies;

a fourth member for contacting the endplate of the other of the adjacent vertebral bodies;

a second rack having a plurality of gear teeth, the second rack contacting one of the third and fourth members;

said axle having a second pinion gear, the axle contacting the other of the third and fourth members, the second pinion gear contacting at least one of the plurality of gear teeth of the second rack such that rotation of the axle moves the third and fourth members from a first spacing of the third member relative to the fourth member to a second spacing of the third member relative to the fourth member .

21. The implant of claim 20 and wherein:

the first member and second member are spaced apart from the third member and the fourth member, respectively, for defining in the intervertebral disc space between the adjacent vertebral bodies, walls of an intermediate chamber in communication with said endplates of both of the adjacent vertebral bodies.

22. The implant of claim 21 and further comprising an osteogenic fusion promoting material disposed within the chamber.

23. The implant of claim 22 and wherein the fusion promoting material is selected from the group consisting of consisting of BMP, LMP, and DBM.

24. A an expandable spinal implant positionable in an intervertebral disc space between the endplates of adjacent vertebral bodies comprising:

a first component having a first longitudinal axis and having members spaced apart along said axis, said members having portions for engagement with the endplate of one of said vertebral bodies, and said members having surfaces for defining walls of a first chamber communicating with said endplate;

a second component having a longitudinal axis and members spaced apart along said second axis, said members of said second component having portions for engagement with the endplate of the other of said vertebral bodies, and said members of said second component having surfaces for defining walls of a second chamber for communicating with the endplate of said other vertebral body; and

a biasing member engaging said first component and said second component for expanding the implant from a first configuration to a second configuration, a first portion of the biasing member being in contact with the first component and a second portion of the biasing member in contact with the second component, the biasing member being compressed when the implant is in the first configuration.

25. An implant as in claim 24, wherein:

the biasing member is selected from a group consisting of a spring, a shape-memory alloy, and a compressible material.

26. An expandable spinal implant for insertion within the disc space between adjacent vertebral bodies, comprising:

a first end member having a first engagement portion spaced apart from a second engagement portion each for engaging the endplate of one of the adjacent vertebral bodies;

a second end member having a third engagement portion spaced apart from a fourth engagement portion each for engaging the endplate of the other one of the adjacent vertebral bodies;

an expansion member contractible with the first end member and the second end member, the expansion member having a first state corresponding to a first spacing between the first end member and second end member along a first axis substantially corresponding to a height of the disc space, and a second state corresponding to a second spacing between the first end member and the second end member along the first axis, wherein the second spacing is greater than the first spacing; and

wherein the first end member and the second end member define an intermediate chamber between the respective engagement portions for communication with the endplates of each of the adjacent vertebral bodies.

27. The spinal implant of claim 26, wherein the expansion member maintains substantially the same position in a plane perpendicular to the first axis in both the first state and the second state.

28. The spinal implant of claim 26, further comprising:

a bone growth inducing material positioned within the intermediate chamber.

29. The spinal implant of claim 26, wherein the expansion member is selected from the group consisting of a cam mechanism, a screw mechanism, a rack-and-pinion mechanism and a biasing mechanism.

30. A spinal implant for insertion within the disc space between adjacent vertebral bodies and comprising:

a first end member having a first portion for engaging an endplate of one of said adjacent vertebral bodies and having a second portion for engaging an endplate of the other of said adjacent vertebral bodies, the first portion and second portion being spaced apart;

a second end member having a third portion for engaging the endplate of one of said adjacent vertebral bodies and having a fourth portion for engaging the endplate of the other of said adjacent vertebral bodies, the third portion being spaced apart from the fourth portion; and

means engaging said first and second end members for changing spacing between said first and second portions and for changing the spacing between said third and fourth portions.

31. The spinal implant of claim 30 and wherein the means for changing the spacing is selected from the group consisting of a cam mechanism, a screw mechanism, a rack and pinion mechanism, and a biasing mechanism.

32. The spinal implant of claim 30 and wherein the means for changing the spacing is selected from a group consisting of a shape-memory alloy, a compressible elastomer, and a metal spring.

33. The spinal implant of claim 30 and further comprising:

an elongate member intermediate said first end member and said second end member for cooperating with faces of said first and second end members to define a chamber between the endplate of said one vertebral body and the endplate of said other vertebral body for receiving bone growth inducing material within said chamber.

34. The combination of claim 33 and further comprising:

bone growth material received between said end members and around said elongate member to fill said chamber.

35. The combination of claim 34 and wherein the bone growth inducing material is selected from a group consisting of bone, BMP, LMP, and DBM.

36. The spinal implant of claim 30 and wherein:

said first and second end members have a cylindrical shape.

37. The spinal implant of claim 30 and wherein:

said first and second end members have a rectangular shape.

38. The spinal implant of claim 30 and wherein said first and second end members have short cylindrical shapes.

39. The spinal implant of claim 30 and wherein:

the first and second end members have short parallelepiped shapes.

40. The spinal implant of claim 30 and further comprising:

an elongate member connected to said first and second end members and having a central axis; and

said first and second end members being cylindrical with axes colinear to the axis of said elongate member.

41. The spinal implant of claim 40 and further comprising:

surface projections from said portions for engaging said vertebral bodies.

42. The spinal implant of claim 30 and further comprising:

an elongate member connected to said end members and having a longitudinal axis; and

said end members are polygonal in spaced planes perpendicular to said longitudinal axis.

43. The spinal implant of claim 42 and wherein:

said portions for engaging said vertebral bodies have surface projections for anchoring in said vertebral bodies.

44. The spinal implant of claim 43 and wherein:

said surface projections are barbs.

45. A method of promoting osteogenic fusion of adjacent spinal vertebral bodies comprising:

providing an implant that defines a chamber intermediate spaced portions of the implant and both of the adjacent vertebral bodies;

providing the implant substantially intermediate the adjacent vertebral bodies; and

expanding the implant in a manner that substantially maintains communication of the adjacent vertebral bodies through the intermediate chamber.

46. The method of claim 30 further comprising:

placing osteogenic fusion promoting material into the chamber.

47. The method of claim 31 wherein:

at least a portion of the osteogenic fusion promoting material is bone.

48. The method of claim 31 wherein:

providing the implant includes providing a first end portion of the implant and a second end portion of the implant and an elongate central portion of the implant extending intermediate the first and second end portions, with the central portion of the implant extending intermediate the first and second end portions and through the chamber; and

the fusion promoting material is selected from a group including bone chips, demineralized bone matrix, hydroxy apatite, and calcium phosphate.

49. The method of claim 48 and wherein:

expanding the implant is performed by changing its state from a first state to a second state by changing the height of the implant in the space between the adjacent vertebral bodies without translation of the implant relative to the vertebral bodies.

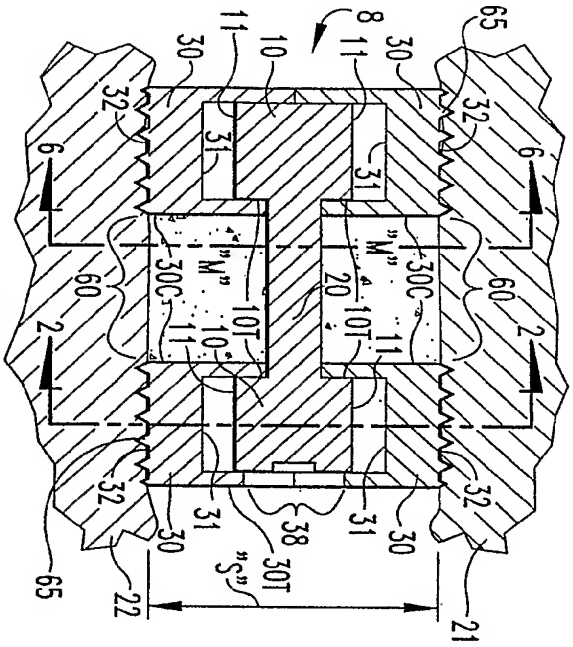


Fig. 1

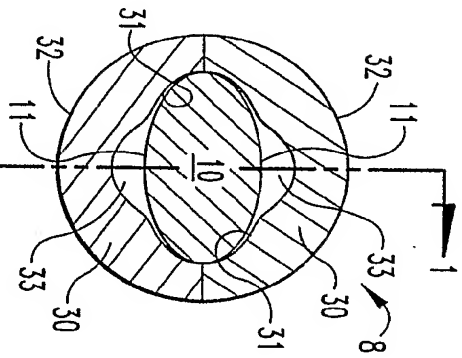


Fig. 2

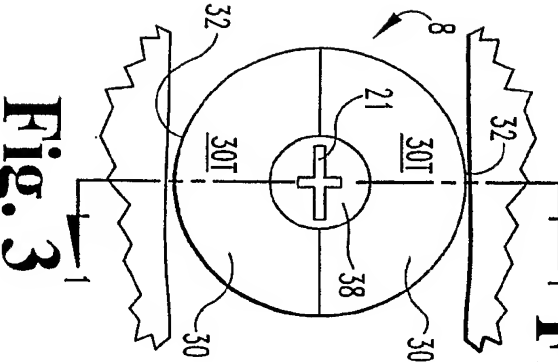


Fig. 3

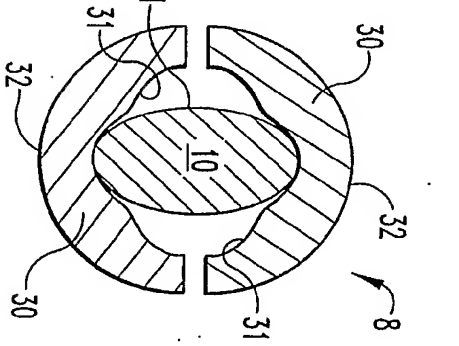


Fig. 4

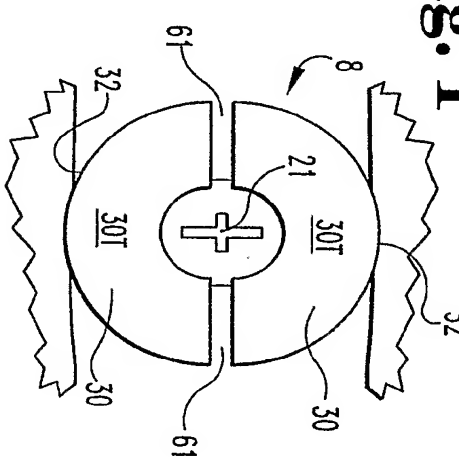


Fig. 5

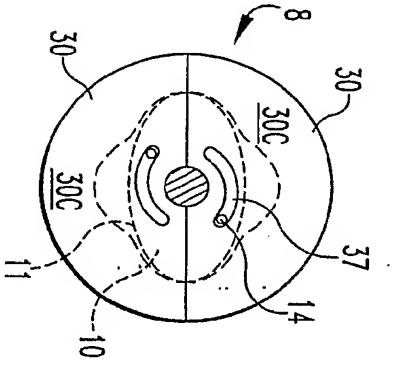


Fig. 6

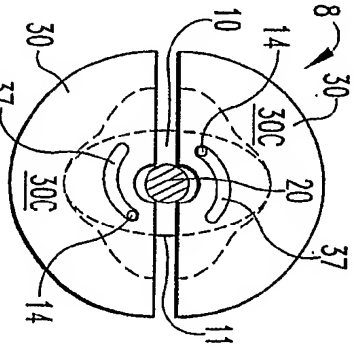


Fig. 7

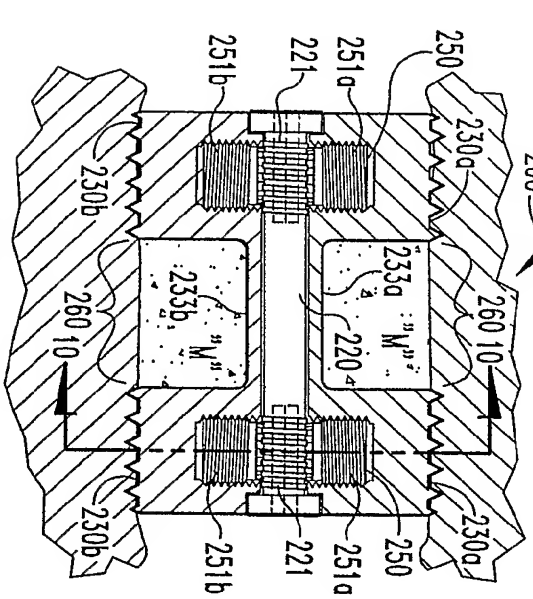


Fig. 8

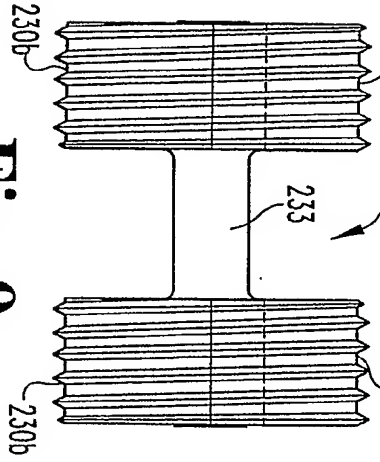


Fig. 9

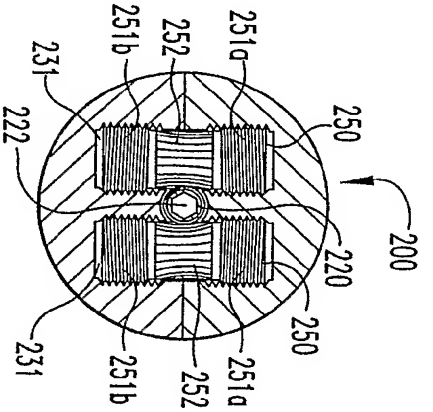


Fig. 10

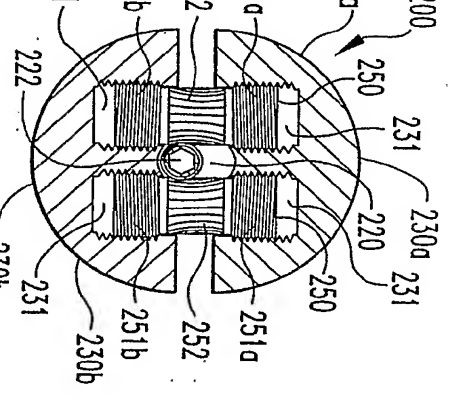


Fig. 11

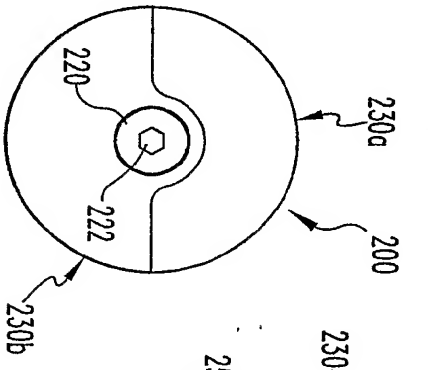


Fig. 12

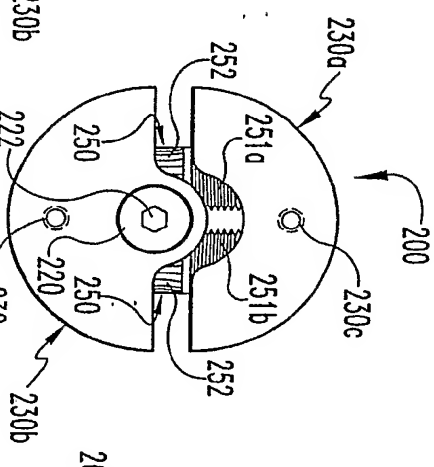


Fig. 13

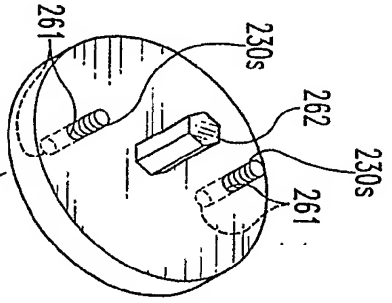
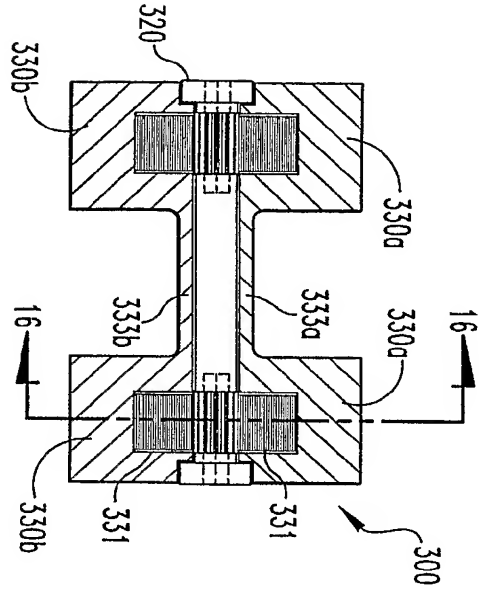


Fig. 14



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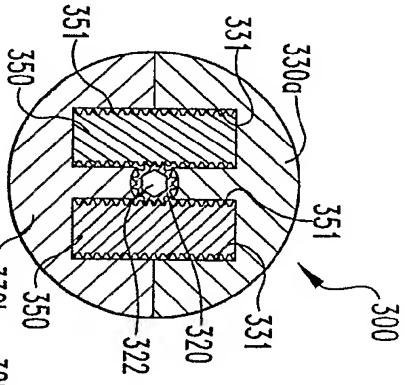

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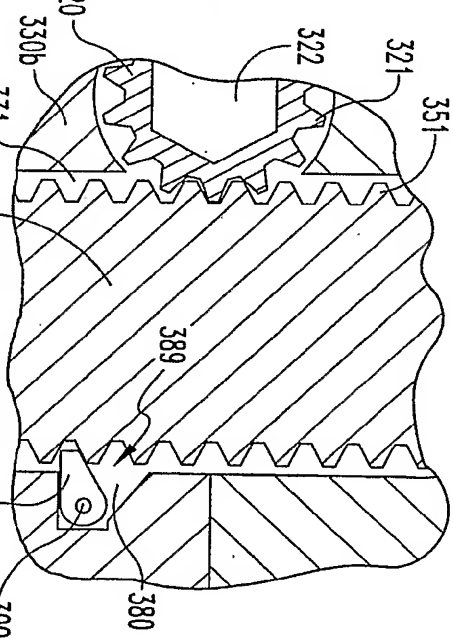

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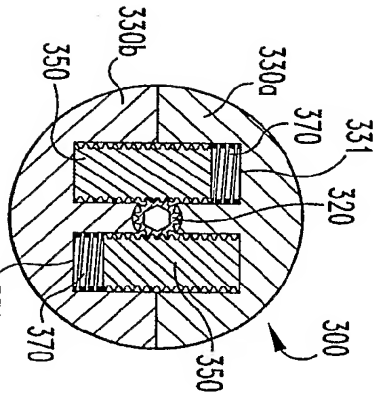

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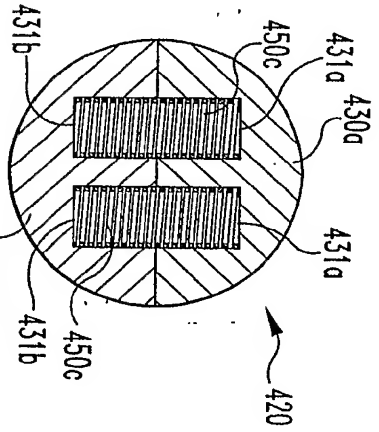

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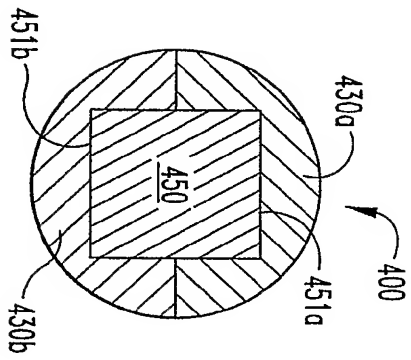

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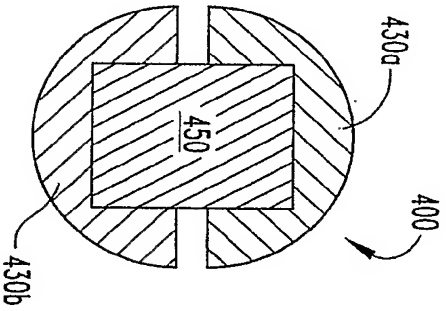

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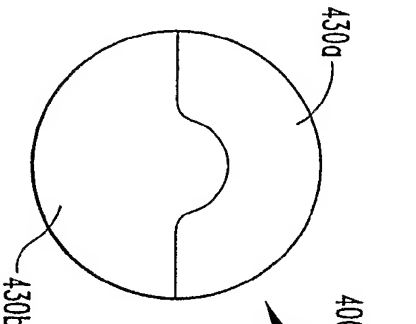

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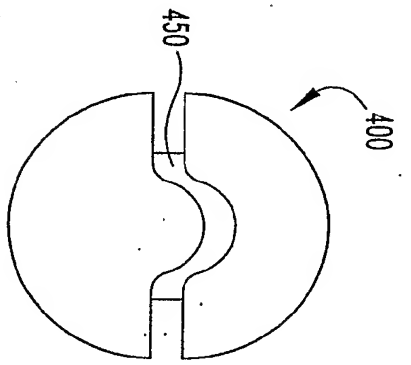

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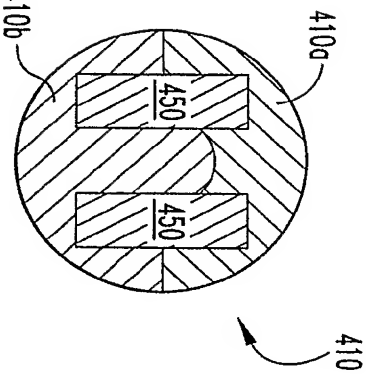

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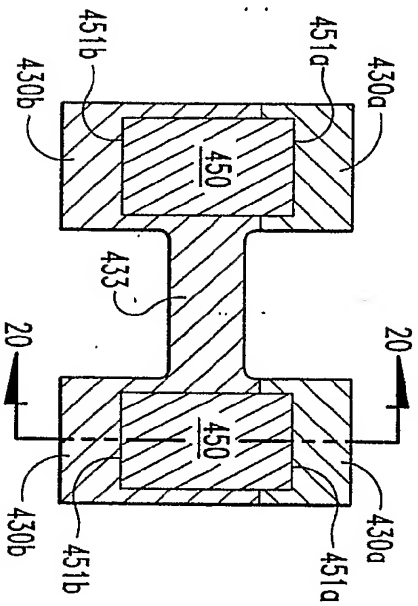

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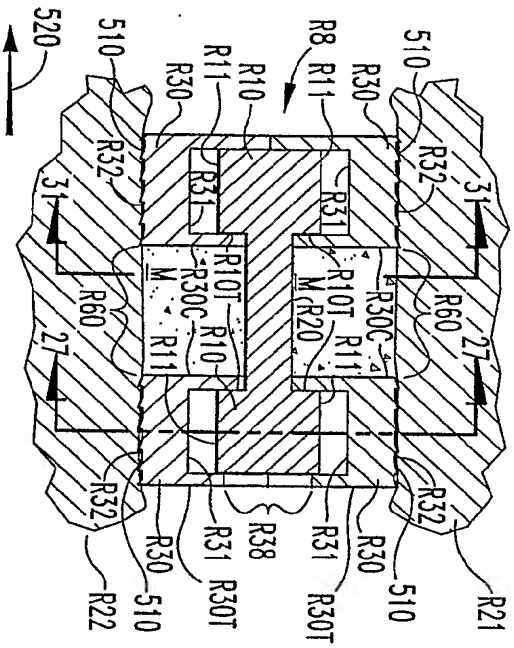

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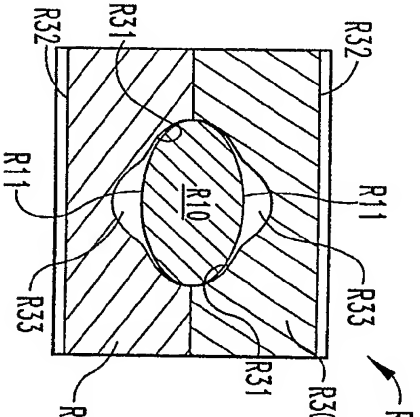

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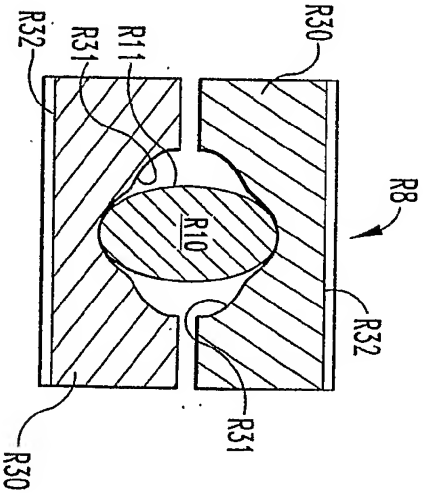

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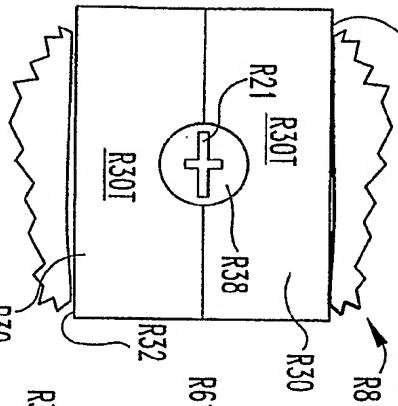

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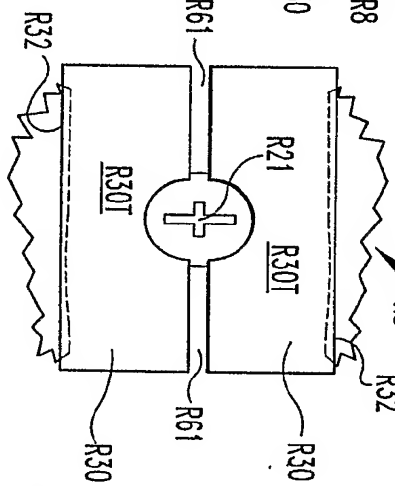

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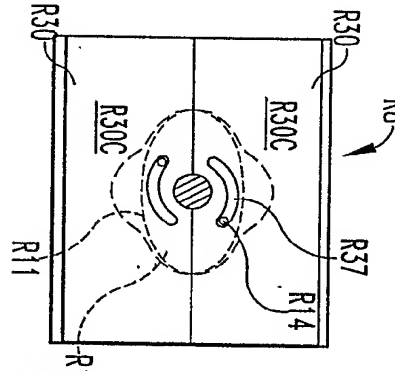

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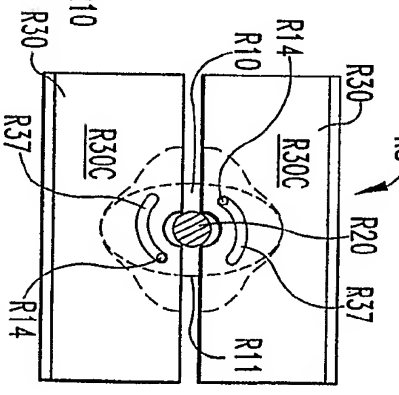

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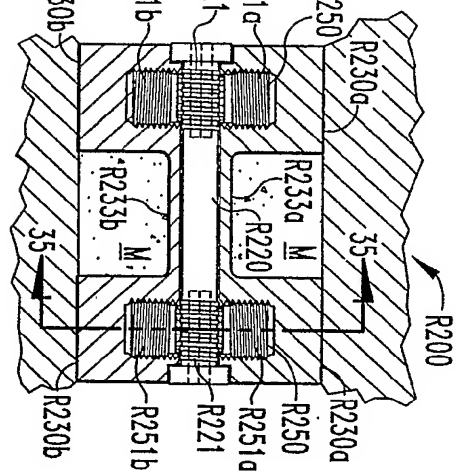

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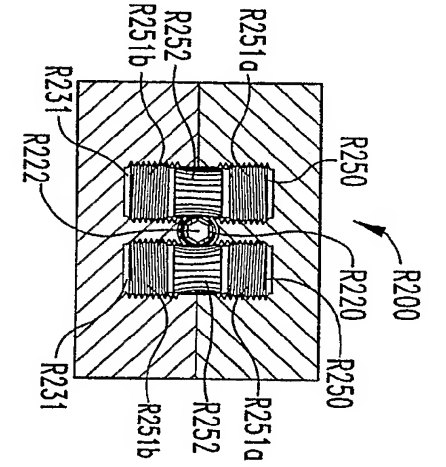

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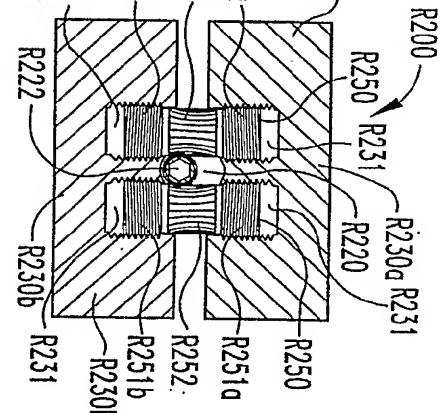

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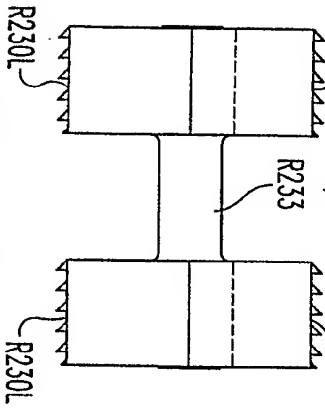

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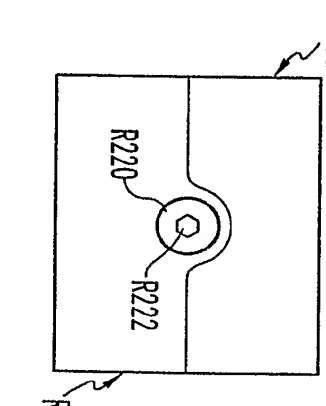

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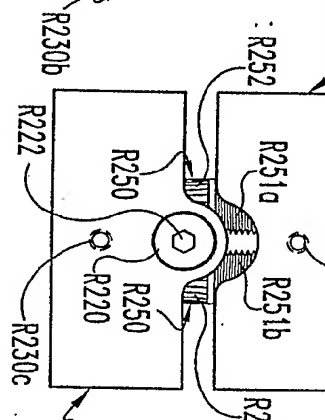

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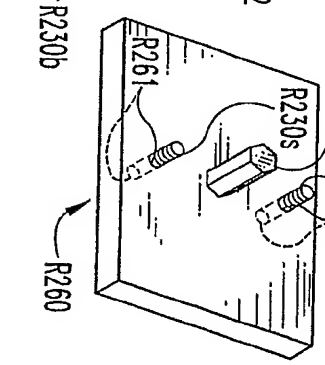

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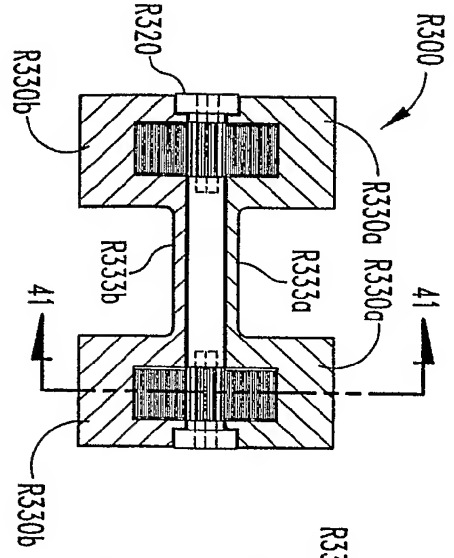

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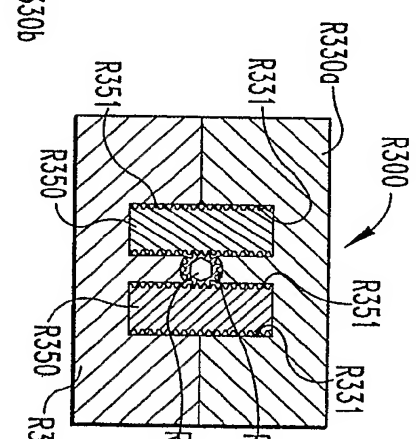

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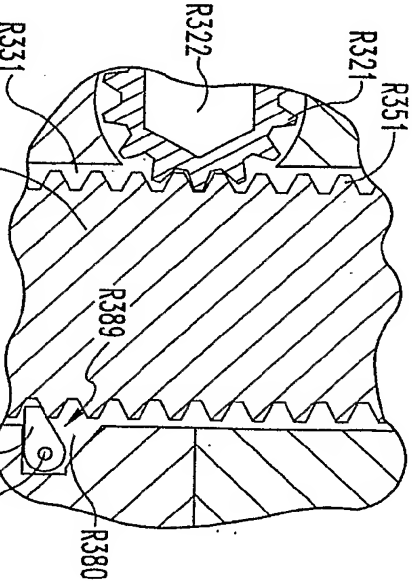

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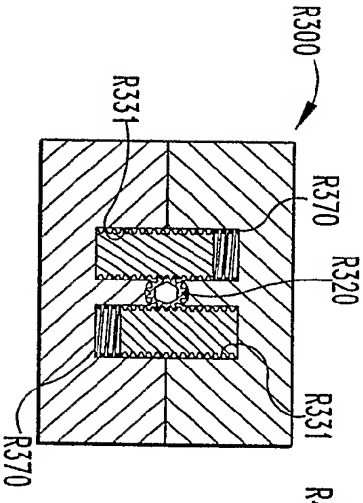

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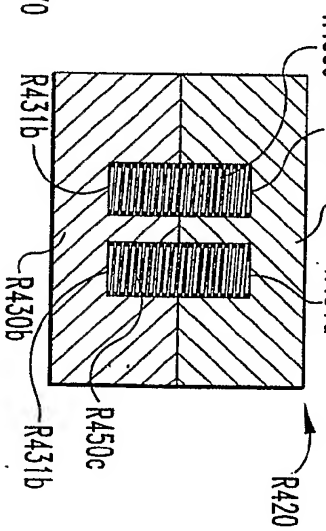

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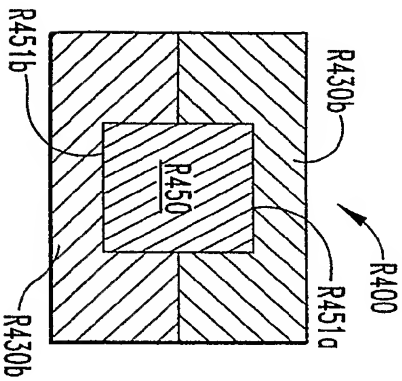

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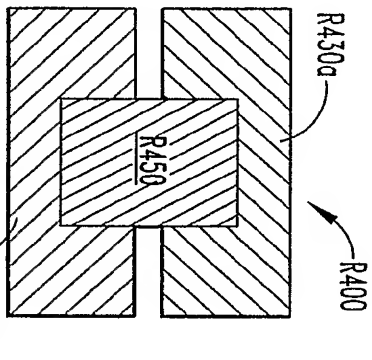

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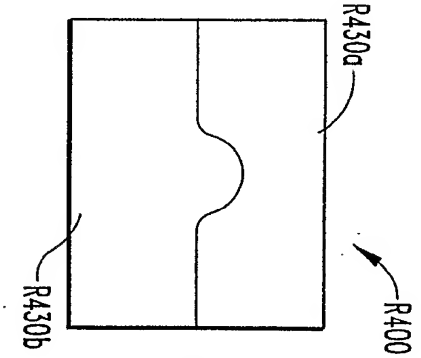

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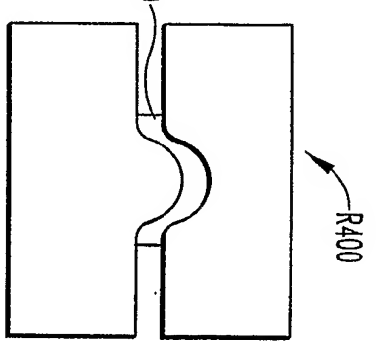

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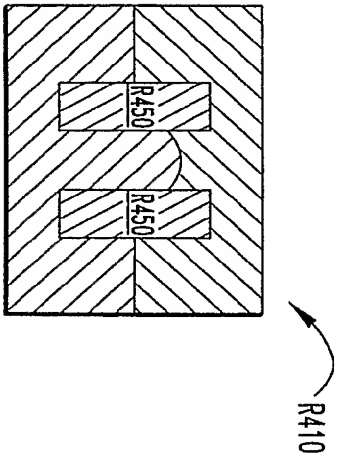

Fig. 50

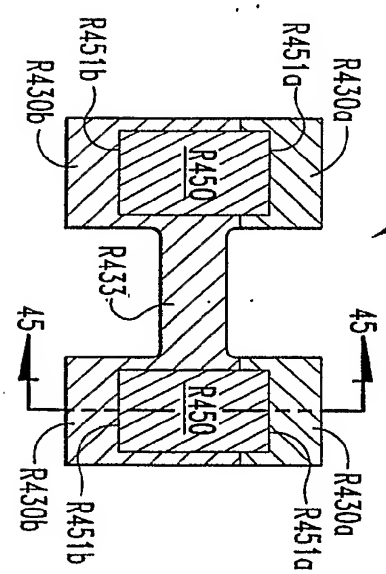

Fig. 49

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— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO*

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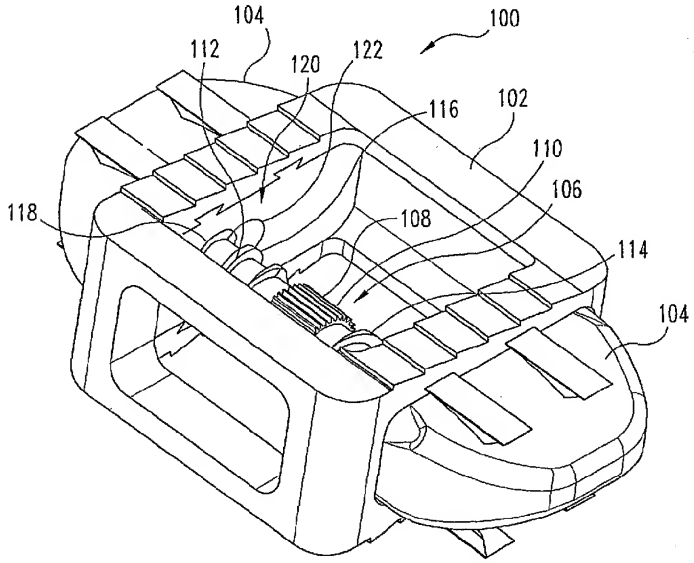
(54) Title: LATERALLY EXPANDABLE CAGE



(57) Abstract: A laterally expandable spinal implant (100) includes a central body (102) and two wings (104) that are adapted to be received within an inner chamber formed within the central body. The wings have guide rails (302) that fit into grooves (304) defined in the central body. To ensure that the implant is properly secured, each guide rail has an outer end with a cutting surface (406) that cuts into vertebral end plates when the wings are extended. The two wings are connected together through a central turnbuckle shaft (108) that has geared teeth and threading on both ends that engage threaded cavities in the wings. Through the gear teeth, the turnbuckle shaft is able to be rotated so as to laterally extend the wings from the central member. A locking mechanism (120) locks the turnbuckle shaft to prevent the wings from retracting.

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patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

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LATERALLY EXPANDABLE CAGE

BACKGROUND

The present invention generally concerns spinal implants, and more specifically, but not exclusively, concerns a laterally expandable vertebral implant.

A major cause of persistent, often disabling, back pain can arise by disruption of the disc annulus, chronic inflammation of the disc, or relative instability of vertebral bodies surrounding a given disc, such as might occur due to a degenerative disease. In the more severe cases, some form of mechanical limitation to the movement of the vertebrae on either side of the subject disc is necessary. In such cases, the disc tissue is irreparably damaged, thereby necessitating removal of the entire disc. However, when the disc nucleus is removed without subsequent stabilization the same disabling back pain often reoccurs due to persistent inflammation and/or instability.

Various approaches have been developed to stabilize the adjacent vertebral bodies following excision of this material. In one approach, two adjacent vertebrae are fused together through a fusion device that is implanted between the vertebrae. Many of these existing implant designs have drawbacks that lower the spinal fusion rates. Among these design drawbacks, one such flaw is that the implants subside into the vertebral end plates, thereby reducing the spacing between the vertebral bodies. With prior fusion devices, and even some prosthetic devices, a large portion of the load is placed against the weakest part of the vertebral body, which can lead to cavitation of the device into the surrounding vertebral endplates with subsequent collapse of the inner discal space and even damage of the vertebrae itself. Another frequent cause for subsistence is created by having a small area of contact between the implant and the endplates. As one should appreciate, the less surface area of contact between the implant and the end plates, the greater the risk of subsistence.

Another flaw of many implants is the lack of stability created after implantation. Stability is crucial to the success of a fusion. The implant must be securely fixated to the vertebral bodies in order to ensure that no movement occurs between the two. If movement does occur between the vertebral bodies and the implant, the bone may not

properly fuse, thereby creating stability problems. Moreover, some designs limit the amount of graft material, which may be able to be used with the implant. The larger area of graft material that is able to contact the endplates, the better chances of a good, solid bone growth between the two vertebrae.

Some designs have created implants in which the majority of the implant is positioned over the harder cortical bone of the apophyseal ring of the vertebrae in order to reduce the chances of subsistence. However, with these designs, the implant is made from multiple separate components that are individually assembled together within the disc space. Each component is implanted separately and then attached to one another within the disc space. As should be appreciated, assembling such an implant in the disc space can be rather difficult. Such implants also tend to lack a stiff central body, which is essential to the stability of the implant as well as entire fusion construct. Moreover, such implants have no mechanism to fix the implant to the vertebral body. Typically, one has to use bone screws to secure the implant to the vertebral bodies, which makes the implantation process more complicated and difficult. In addition, such implants generally have a single lateral width, and therefore, it is generally very difficult, if not impossible, to adjust for differently sized vertebrae. Another flaw is that these designs typically do not provide a mechanism for ensuring that the spacers are properly positioned. Since the lateral spacers of these types of implants are independently assembled within the disc space, the lateral members can be positioned at unequal positions along the apophyseal ring, thereby increasing the risk that the implant will subside into the vertebral end plates.

SUMMARY

In one aspect, a spinal implant includes a cage defining an interior cavity and an expansion mechanism received in the cavity of the cage. A pair of wings are operatively coupled to the expansion mechanism, and the wings each have opposing vertebrae engaging surfaces that are configured to engage opposing vertebrae. The expansion mechanism is operable to laterally move the wings between the vertebrae from a compact configuration in which at least a majority of the wings are received in the cavity of the cage to an expanded configuration in which the wings extend from the cage with the vertebrae engaging surfaces on each of the wings engaging the vertebrae.

Another aspect concerns a fusion device for implanting between opposing vertebrae that define a disc space. The device includes a central member and at least one pair of lateral members slidably coupled to the central member. The device further includes means for extending the lateral members from the central member into the disc space between the vertebrae with each of the lateral members engaging both of the vertebrae.

In a further aspect, an apparatus includes a spinal implant. The spinal implant includes a central member defining an interior cavity and a pair of openings defined on opposite sides of the central member that open into the interior cavity. A pair of wings are slidably received in the openings in the central member. A shaft is coupled to the wings, and the shaft has at least one threaded portion threadedly engaging at least one of the wings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top perspective view of a spinal implant according to one embodiment in an expanded configuration.

FIG. 2 is an exploded view of the FIG. 1 implant.

FIG. 3 is a top perspective view of the FIG. 1 implant in a compact configuration.

FIG. 4 is an end view of the FIG. 1 implant in a compact configuration.

FIG. 5 is a top perspective view of the FIG. 1 implant in an expanded configuration.

FIG. 6 is an end view of the FIG. 1 implant in an expanded configuration.

FIG. 7 is a perspective view of the FIG. 1 implant attached to an inserter tool.

FIG. 8 is an enlarged, perspective view of the FIG. 1 implant coupled to the FIG. 7 tool.

FIG. 9 is a partial cross-sectional view of the FIG. 1 implant positioned in an interdiscal space in an expanded configuration.

FIG. 10 is a side view of the FIG. 1 implant in the interdiscal space.

FIG. 11 is a top view of the FIG. 1 implant in the interdiscal space.

FIG. 12 is a perspective view of a spinal implant according to another embodiment.

DETAILED DESCRIPTION

For the purposes of promoting an understanding of the principles of the present invention, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is intended thereby. Any alterations and further modification in the described processes, systems, or devices, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates. Some embodiments of the invention are shown in great detail, although it will be apparent to those skilled in the relevant art that some of the features may not be shown for the sake of clarity.

A laterally expandable spinal implant 100 according to one embodiment of the present invention will now be described with reference to FIGS. 1-6. As shown in FIGS. 1 and 2, the implant 100 includes a central member or cage 102, a pair of lateral members or wings 104 that are adapted to laterally extend from the cage 102, and an expansion mechanism 106 (or means) that is operable to extend the wings 104. In the illustrated embodiment, the expansion mechanism 106 includes a turnbuckle or threaded shaft 108 that connects the wings 104 together. In other embodiments, the expansion mechanism can include hydraulic pistons, mechanical linkages, and the like. The shaft 108 includes a gear 110 that is centrally located on the shaft 108 between opposing threaded portions 112 and 114. In one embodiment, threads 116 on the threaded portions 112 and 114 are oppositely threaded (i.e., one is a left handed thread and the other is a right handed thread.) In one form of the present invention, the threads 116 of the threaded portions 112 and 114 have an equal pitch such that the wings 104 are able to extend from the central member 102 at the same rate. This ensures that the implant 100 has a symmetrical configuration, which in turn aids in centering the implant 100 over the vertebrae. The threaded portions 112 and 114 threadedly engage threaded openings 118 that are defined in each of the wings 104. In another embodiment, only one end of the shaft 108 is threaded, while the other end of the shaft 108 is unthreaded. With this embodiment, the wings 104 are still extended by rotating the shaft 108.

Implant 100 further includes a lock mechanism 120 that is used to lock the wings 104 in an expanded configuration in which the wings 104 laterally extend from the cage 102. In the embodiment illustrated in FIG. 1, the lock mechanism 120 includes lock cavities 122 that are defined in each of the wings 104 next to the threaded openings 118. As illustrated in FIG. 2, the lock cavities 122 open into the threaded opening 118 in the wings 104. In one embodiment, each lock cavity 122 is only partially threaded such that once the wings 104 are in the expanded configuration, the shaft 108 can be slid from the threaded opening 118 into the lock cavity 122. By being only partially threaded near the entrance of the cavity 122, the shaft 108 is unable to rotate such that the wings 104 are unable to be retracted. In another embodiment, the lock cavity 122 is unthreaded, but has a depth shallower than the threaded openings 118 so as to keep the wings 104 in the expanded configuration, when the shaft is moved into the lock cavities 122.

Referring to FIG. 2, each wing 104 includes opposing vertebrae engaging surfaces 202 that are configured to engage opposing vertebrae, as well as medial 204 and lateral 206 side surfaces. As shown, the wings 104, according to the illustrated embodiment, have a generally tapered shape so as to coincide with the vertebral endplate geometry. The vertebrae engaging surfaces 202 generally taper from the medial sides 204 to the lateral sides 206. To further reduce trauma upon insertion of the implant 100, the wings 104 have beveled edges 208 between the vertebrae engaging surfaces 202 and the lateral surfaces 206. In the illustrated embodiment, the medial sides of the wings 104 are generally flat so as to allow the wings 104 to contact one another in a compact state when the wings 104 are retracted within the cage 102. The medial sides 204 of the wings 104 define access channels 210 around the threaded opening 114 and the lock cavity 122. In one form, access channel 210 is sized to receive the gear 110 on the shaft 108. The access channel 210 has an opening 212 that allows the physician to gain access and rotate the gear 110 so as to expand the implant 100. In the illustrated embodiment, the lateral sides 206 have a generally curved shape in order to coincide with the shape of the apophyseal ring of the vertebrae.

With continued reference to FIG. 2, the cage 102 has a proximal or tool engaging end wall portion 214, an opposite distal end wall portion 216, and a pair of opposing lateral wall portions 218 that together define an interior cavity 220. The cage 202 further

has a pair of opposing vertebrae engaging surfaces 222 that are configured to engage opposing vertebrae. To coincide with vertebrae geometry, surfaces 222 in the illustrated embodiment are tapered such that surfaces 222 angle towards one another from the proximal end wall portion 214 to the distal end wall portion 216. As shown, the interior cavity 220 extends through both vertebrae engaging surfaces 222. In the illustrated embodiment, the cage 102 has a generally rectangular shape. The vertebrae engaging surfaces 222 can include texturing so as to prevent expulsion of the implant 100 from the vertebrae. For instance, the vertebrae engaging surfaces 222 in the illustrated embodiment have ridges 224 that aid in preventing expulsion of the implant 100. As should be appreciated, in other forms of the present invention, the vertebrae engaging surfaces 222 can include other types of texturing for preventing expulsion of the implant 100. The proximal end wall portion 214 defines a tool opening 226 through which an insertion tool can be inserted into the interior cavity 220, and lateral walls 218 define wing openings 228 through which the wings 104 are slidably received into the interior cavity 220.

FIGS. 3 and 4 illustrate the implant 100 when in a compact state in which the wings 104 are retracted inside the interior cavity 220. As shown in FIG. 3, the wings 104 have one or more guide rails 302 that engage corresponding guide channels 304 formed around the wing openings 228. In the illustrated embodiment, each wing 104 has four guide rails, with a pair positioned along each opposing vertebrae engaging surface 202 of the wing 104. In order to provide further stability, the guide rails 302 and the corresponding channels 304 in the illustrated embodiment have a general dovetail shape. Moreover, as discussed in further detail below, the dovetail shape of the guide rails 302 ensure that the wings 104 remain secure in the vertebrae once implanted. When the implant 100 is in a compact state, the majority of the wings 104 are received in the interior cavity 220 of the cage 102. In the compact state, the medial sides 204 contact each other and the entrances 212 of the access channels 210 define an access opening 306 through which an insertion tool can gain access to gear 110 on shaft 108 in order to rotate the shaft 108.

As previously mentioned, the gear 110 is used to rotate the shaft 108, thereby causing the wings 104 to extend from the cage 102. FIGS. 5 and 6 show the implant 100 with the wings 104 in a laterally expanded state in which the wings 104 extend from the

cage 102. As should be appreciated, the expansion mechanism 106 allows the wings 104 to extend at varying distances from the cage 102 such that the size of the implant 100 can be adjusted to correspond to the size of the selected vertebrae. As shown in FIG. 6, outer lateral ends 402 of the guide rails 302 define an inward notch 404 such that the outer lateral ends 402 form cutting edges 406. As the wings 104 are extended, the cutting edges 406 cut channels into the vertebrae. The cutting edges 406 act like spikes to embed the wings 104 into the vertebral endplates. Once the wings 104 are extended, the dovetail shape of the guide rails 302 help to ensure that the wings 104 are firmly secured to the vertebrae. Once the wings 104 are in the desired extended position, the shaft 108 is then slid into the lock cavity 122 (FIG. 2) in order to lock the wings 104 in the desired extended position. After implantation, bone graft material can be packed into the interior cavity 220 via tool opening 226 to promote fusion of the vertebrae. With the wings 104 slightly extended, bone graft material can even be packed before implantation. Following implantation, the interior cavity 220 provides a large area in which a fusion mass can be formed between the vertebrae.

An implant inserter assembly 700 that includes the implant 100 coupled to an inserter 702 according to one embodiment of the present invention is illustrated in FIGS. 7 and 8. The inserter 702 includes a driving handle 704, an actuation knob 706, a shaft portion 708, a gripping knob 710 and a head portion 712. In the illustrated embodiment, the handle portion 704 is solid and includes an impaction surface 714 against which a hammer or the like can strike to drive implant 100 between the vertebrae. The actuation knob 706 is connected to a drive shaft 802, which extends from the actuation knob 706, through the shaft 708, and through the head 712. When the implant 100 engages the inserter 702, the actuation knob 706 is able to extend the wings 104. As shown in FIG. 8, the drive shaft 804 has at one end a drive gear 804 with teeth 806 that engage an intermediate gear 808 that is coupled to the head 712 through a carrier member 810. During implantation, the intermediate gear 808 engages gear 110 on the shaft 108 of the implant 100. As the actuation knob 706 is rotated, the drive shaft 802 rotates drive gear 804. In turn, the drive gear 804 rotates the intermediate gear 808, which then is used to rotate the shaft 108 in order to extend the wings 104. The gripping knob 710 is rotated in order to extend gripping fingers 812 inside the interior cavity 220 such that the inserter

702 engages the tool opening 226 of the implant 100. The gripping knob 710 and the gripping fingers 812 can be optional, such that in one embodiment knob 710 and fingers 812 are not included. To provide a large surface area for impaction, the head 712 has a generally rectangular shape to generally coincide with the shape of the proximal end wall portion 214 of the implant 100.

FIGS. 9, 10 and 11 show various views of the implant 100 when implanted between adjacent vertebrae 902 and 904. Before implantation, a portion of the annulus is removed to create a larger disc space for the implantation of the implant 100. The vertebral end plates are prepared by removing cartilaginous material connected to them. A window 906, which generally corresponds in shape and size to the cage 102, is formed in both vertebrae 902 and 904. Before implantation, the wings 104 are positioned in their retracted position inside the interior cavity 220 of the implant 100, and the implant 100 is attached to the inserter 702 in the manner as illustrated in FIG. 7. The implant 100 is then impacted into the window 906 formed between vertebrae 902 and 904. Rotation of the actuation knob 706 on the inserter 702 causes the shaft 108 on the implant 100 to rotate, thereby expanding the implant 100. As previously mentioned, this causes the wings 104 to laterally expand from the cage 102 between the vertebrae. In one embodiment, the wings 104 are extended from the cage 102 at the same rate to ensure that the implant 100 remains centered between the vertebrae 902 and 904. As the wings 104 extend, the cutting edges 406 of the guide rails 302 cut into the vertebrae 902 and 904, thereby ensuring that the implant is securely fastened to the vertebrae 902 and 904. The wings 104 are expanded until they are positioned over the apophyseal ring, which contains the harder cortical bone. As shown in FIG. 9, the shape of the wings 104 generally correspond to the geometry of the end plates of vertebrae 902 and 904. Due to the large surface area provided by the implant 100 and by being supported on the harder cortical bone of the apophyseal ring, the risk of subsidence of the implant 100 into the vertebrae 902 and 904 is reduced. Moreover, the construction of implant 100 allows for the implant to have variable dimensions such that the implant 100 can accommodate vertebrae of varying sizes. Once the implant 100 has been expanded to the desired expansion configuration, the turnbuckle 108 can be moved into the block cavity 122 such that the wings 104 are locked into position.

Referring to FIG. 12, an implant 1200 according to another embodiment of the present invention incorporates a number of the same features described above, with the exceptions noted below. As should be appreciated, the locking mechanism 120 in this embodiment differs from the one described above. In the embodiment illustrated in FIG. 12, the locking mechanism 120 includes a leaf spring 1202 that is attached to the distal end wall portion 216 of the cage 102. As shown, the leaf spring 1202 engages the gear 110 on the shaft 108. The leaf spring 1202 is positioned such that the shaft 108 can only be rotated in one direction so that the wings 104 can only move in a laterally expanding direction. The spring 1202 resists rotation of the shaft in the opposite direction, so that once the wings 104 are extended to the desired location the spring 1202 locks the wings 104 into position.

While specific embodiments of the invention have been shown and described in detail, the breadth and scope of the present invention should not be limited by the above described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents. It is understood that only selected embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A spinal implant, comprising:

a cage defining an interior cavity;

an expansion mechanism received in said cavity of said cage;

a pair of wings operatively coupled to said expansion mechanism, said wings each having opposing vertebrae engaging surfaces that are configured to engage opposing vertebrae; and

wherein said expansion mechanism is operable to laterally move said wings between the vertebrae from a compact configuration in which at least a majority of said wings are received in said cavity of said cage to an expanded configuration in which said wings extend from said cage with said vertebrae engaging surfaces on each of said wings engaging the vertebrae.

2. The implant of claim 1, wherein said expansion mechanism includes a shaft having threaded portions on opposite ends that threadedly engage said wings.

3. The implant of claim 2, wherein said shaft includes a gear positioned between said threaded portions for rotating the shaft.

4. The implant of claim 2, wherein said threaded portions are oppositely threaded and have equal thread pitch.

5. The implant of claim 2, further comprising a lock mechanism operable to lock said wings in said expanded configuration.

6. The implant of claim 5, wherein:

said lock mechanism includes lock cavities defined in said wings; and

said lock cavities are configured to prevent rotation of said shaft when said shaft is positioned within said lock cavities.

7. The implant of claim 6, wherein only a portion of each of said lock cavities is threaded.

8. The implant of claim 5, wherein said lock mechanism includes a leaf spring engaged to said cage, said leaf spring being operable to at least prevent rotation of said shaft in one direction.

9. The implant of claim 8, wherein said shaft includes a gear engageable with said leaf spring.

10. The implant of claim 1 further comprising a lock mechanism to lock said wings in an expanded configuration.

11. The implant of claim 10, wherein said lock mechanism included lock cavities constructed and arranged to lock said wings in said expanded configuration.

12. The implant of claim 10, wherein said lock mechanism includes a leaf spring coupled to said cage.

13. The implant of claim 1, wherein said cage has a generally rectangular cross-sectional shape.

14. The implant of claim 1, wherein said cage defines a tool opening for providing access to said cavity.

15. The implant of claim 1, wherein said cage defines wing openings on opposite sides of said cage in which said wings are slidably received.

16. The implants of claim 15, wherein:

at least one of said wing openings defines a guide channel; and

at least one of said wings has a guide member slidably received in said guide channel.

17. The implants of claim 16, wherein said guide member has a dovetail cross-sectional shape.

18. The implant of claim 17, wherein said guide member has a cutting edge operable to cut one of the vertebrae during extension of said wings.

19. The implant of claim 16, wherein said guide member has a cutting edge operable to cut one of the vertebrae during extension of said wings.

20. The implant of claim 1, wherein:

the vertebrae have apophyseal rings; and

said wings have a generally arcuate shape to coincide with the shape of the apophyseal rings of the vertebrae.

21. The implant of claim 1, wherein said cage has opposing surfaces configured to engage the vertebrae.

22. The implant of claim 21, wherein said opposing surfaces are textured surfaces to prevent expulsion of said implant.

23. The implant of claim 22, wherein said textured surfaces include ridges.

24. The implant of claim 1, wherein said vertebrae engaging surfaces of said wings are contoured to correspond in shape to the vertebrae.

25. The implant of claim 1, wherein at least one of said wings has a guide rail received in a guide rail channel defined in said cage.

26. The implant of claim 25, wherein said guide rail has a dovetail cross-sectional shape.

27. The implant of claim 25, wherein said guide rail has an outer cutting edge constructed and arranged to cut the vertebrae during extension of said wings.

28. The implant of claim 1, wherein said cage has oppositely facing vertebrae engagement surfaces and said interior cavity extends between said vertebrae engagement surfaces of said cage.

29. The implant of claim 1, wherein wings define an access opening for allowing access to said expansion mechanism when said wings are in said compact configuration.

30. A fusion device for implanting between opposing vertebrae that define a disc space, comprising:

a central member;

at least one pair of lateral members slidably coupled to said central member; and

means for extending said lateral members from said central member into the disc space between the vertebrae with each of said lateral members engaging both of the vertebrae.

31. The fusion device of claim 30, wherein said means for extending said lateral members includes a shaft with threaded portions coupled to said lateral members.

32. An apparatus, comprising:

a spinal implant including

a central member defining an interior cavity and a pair of openings defined on opposite sides of said central member that open into said interior cavity,

a pair of wings slidably received in said openings in said central member, and

a shaft coupled to said wings, said shaft having at least one threaded portion threadedly engaging at least one of said wings.

33. The apparatus of claim 32, wherein:

said openings have guide channels; and

said wings have guide rails slidably received in said guide channels.

34. The apparatus of claim 32, wherein said at least one threaded portion has a pair of oppositely threaded portions at opposite ends of said shaft.

35. The apparatus of claim 32, further comprising an inserter engaged with said implant to extend said wings.

36. The apparatus of claim 35, wherein said shaft on said spinal implant includes a gear.

37. The apparatus of claim 36, wherein said inserter includes:

an actuation knob;

a drive shaft coupled to said knob;

a drive gear coupled to said drive shaft; and

an intermediate gear engaging said drive gear and said gear on said shaft of said spinal implant.

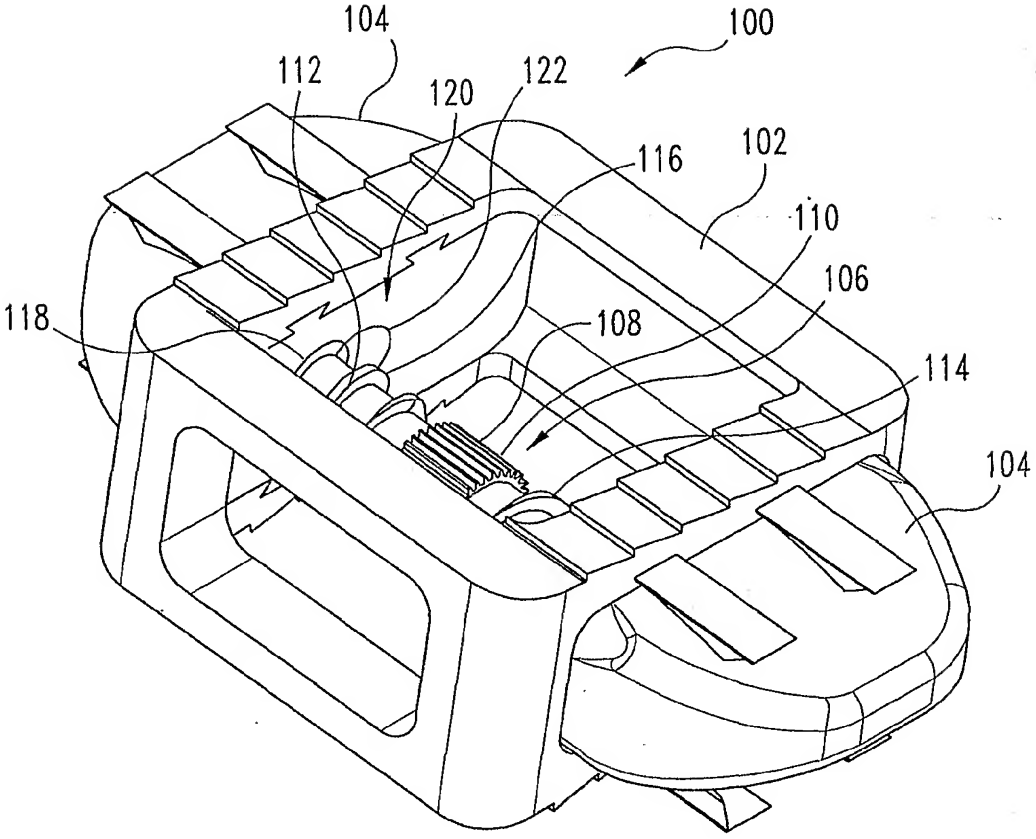

Fig. 1

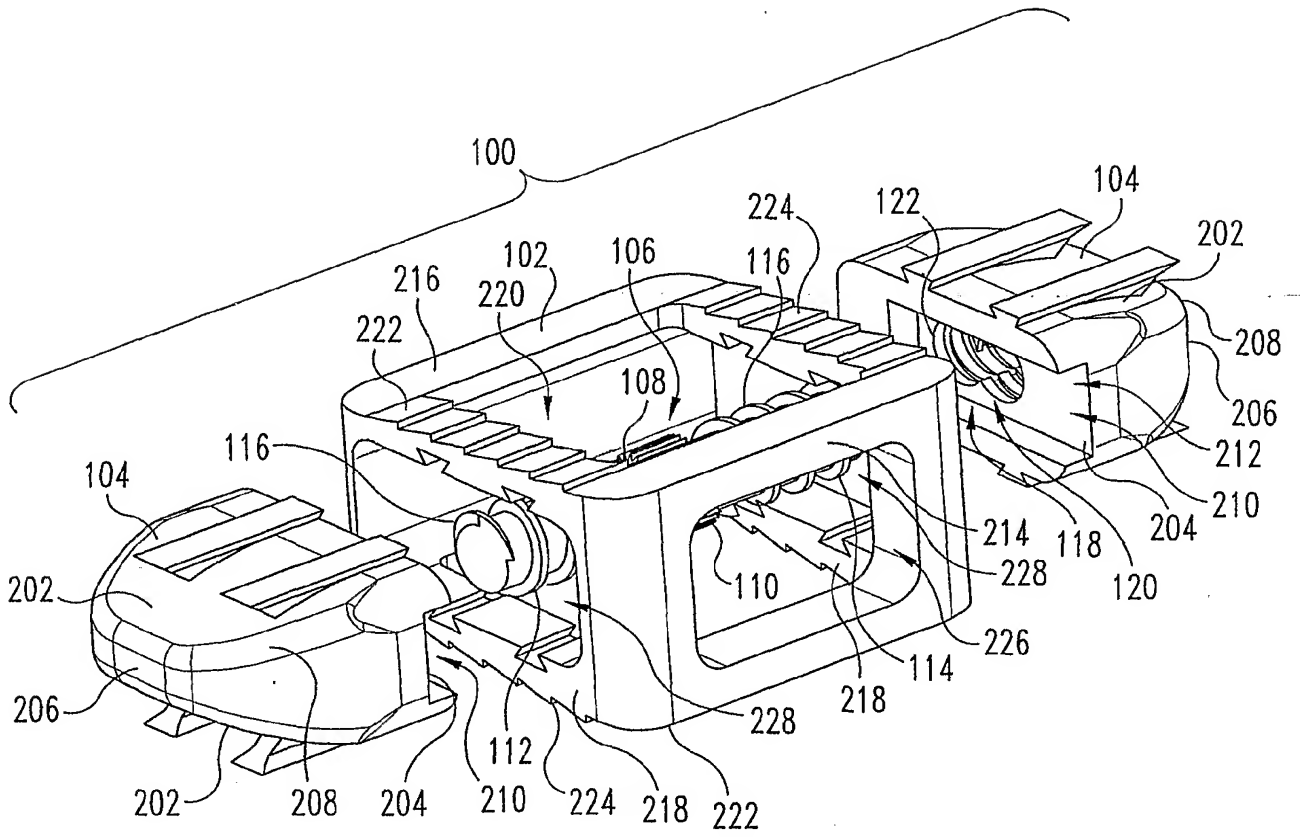
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Fig. 2

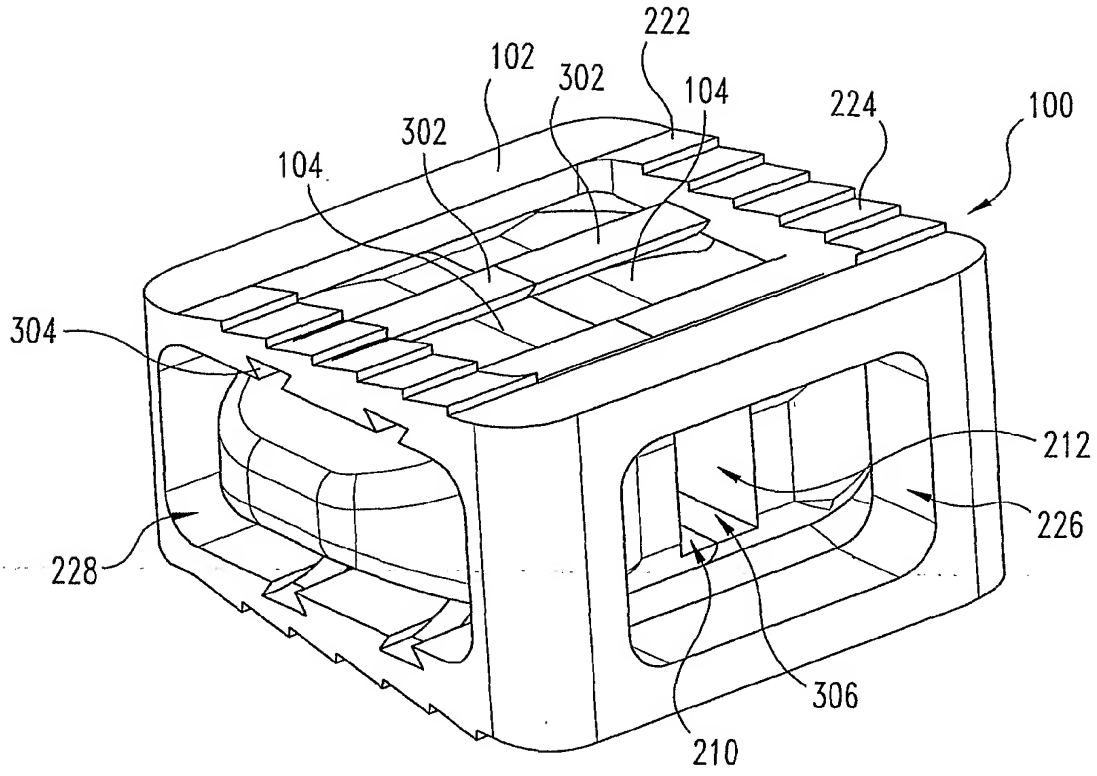
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Fig. 3

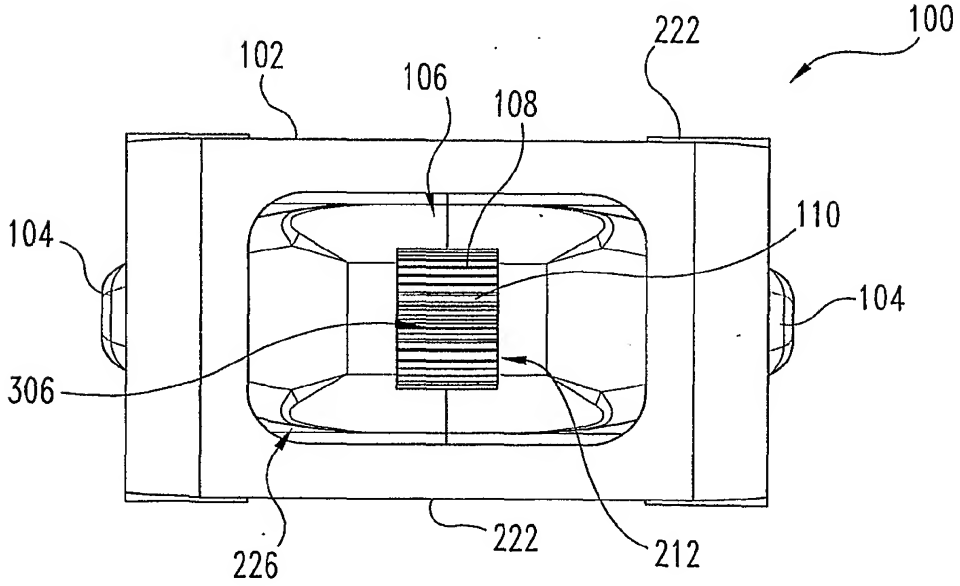
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Fig. 4

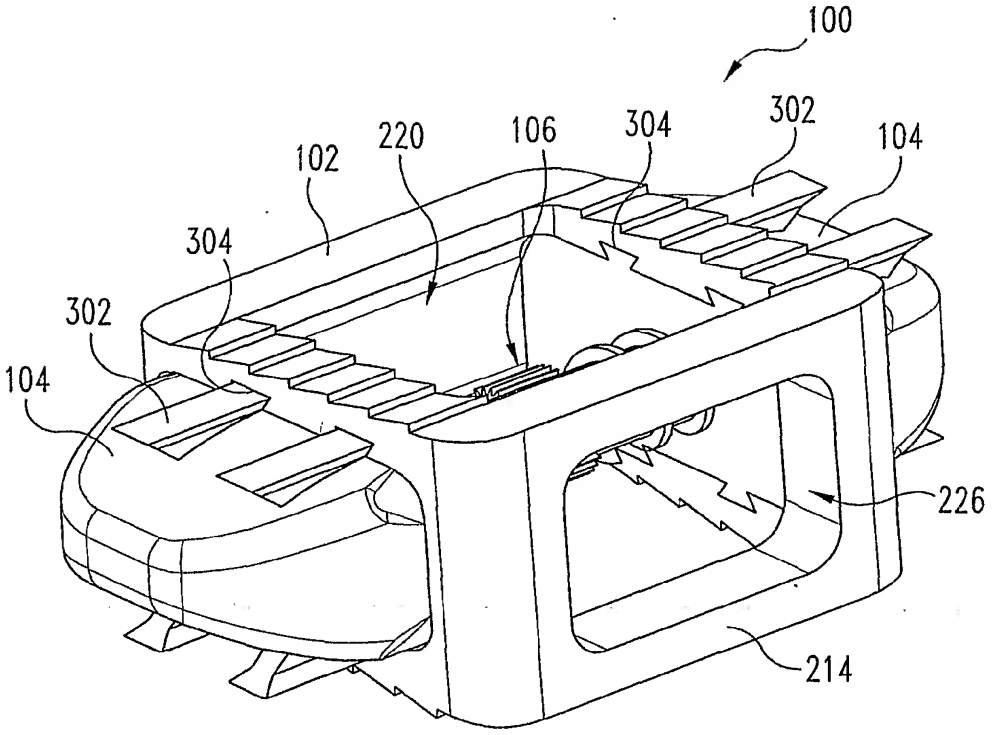
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Fig. 5

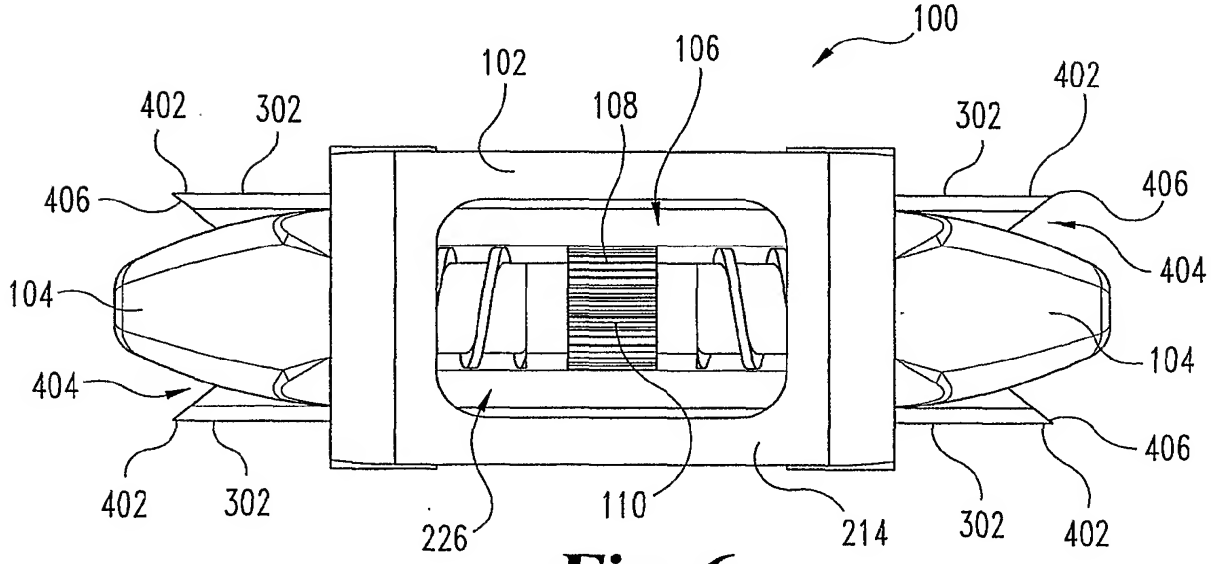
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Fig. 6

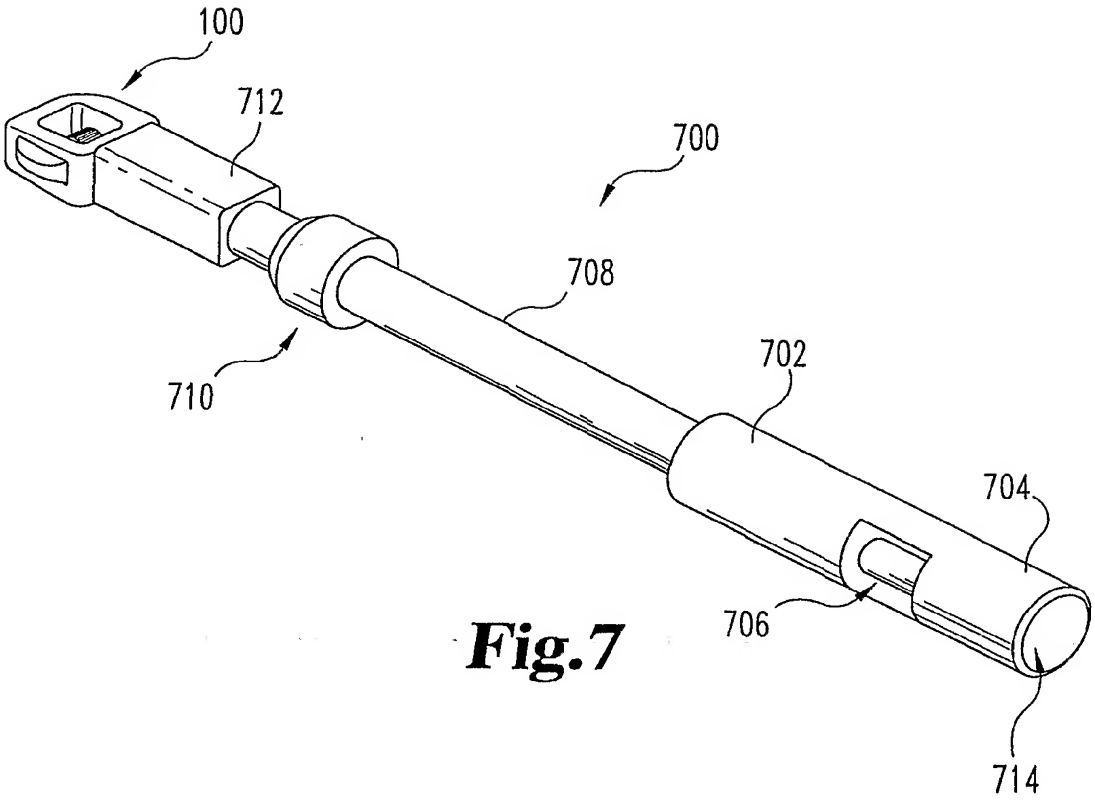
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Fig.7

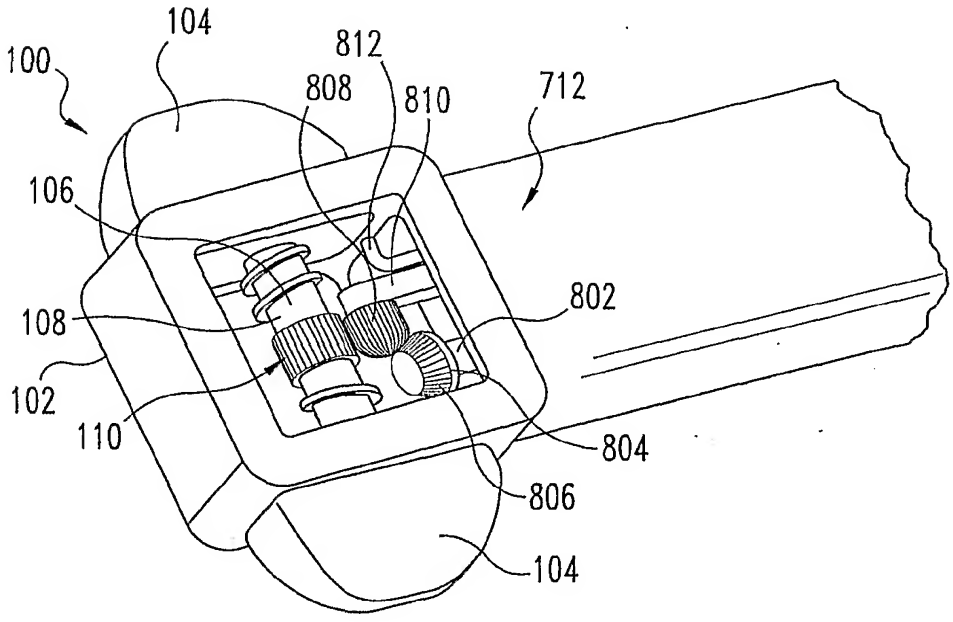
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Fig.8

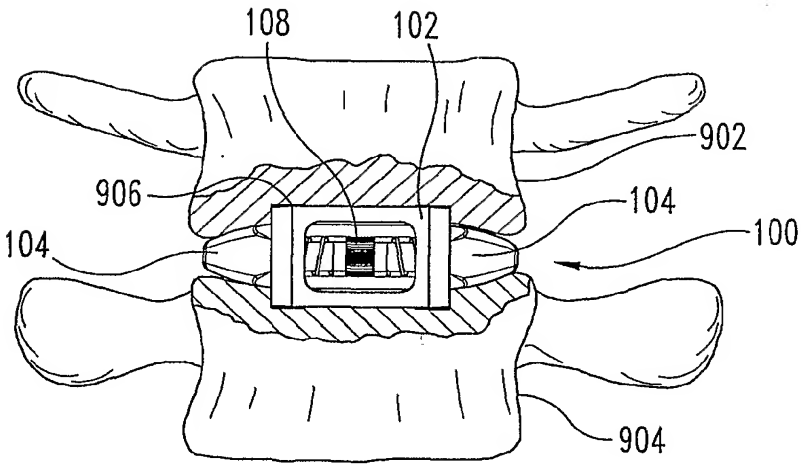

Fig. 9

Fig. 10

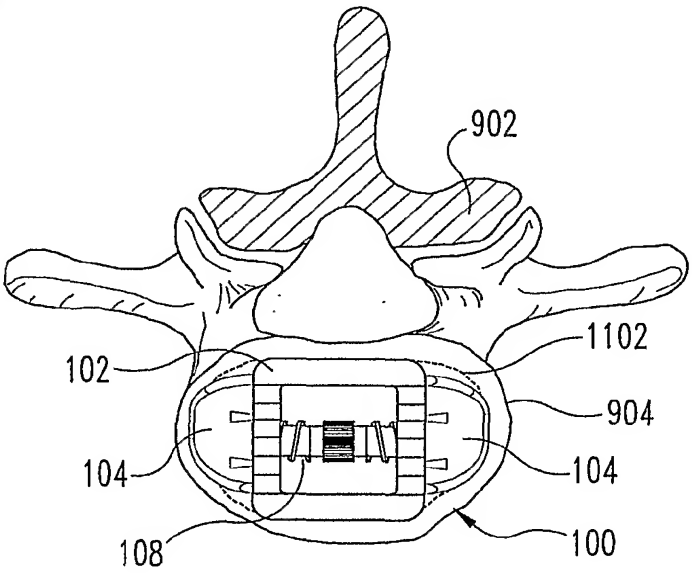

Fig. 11

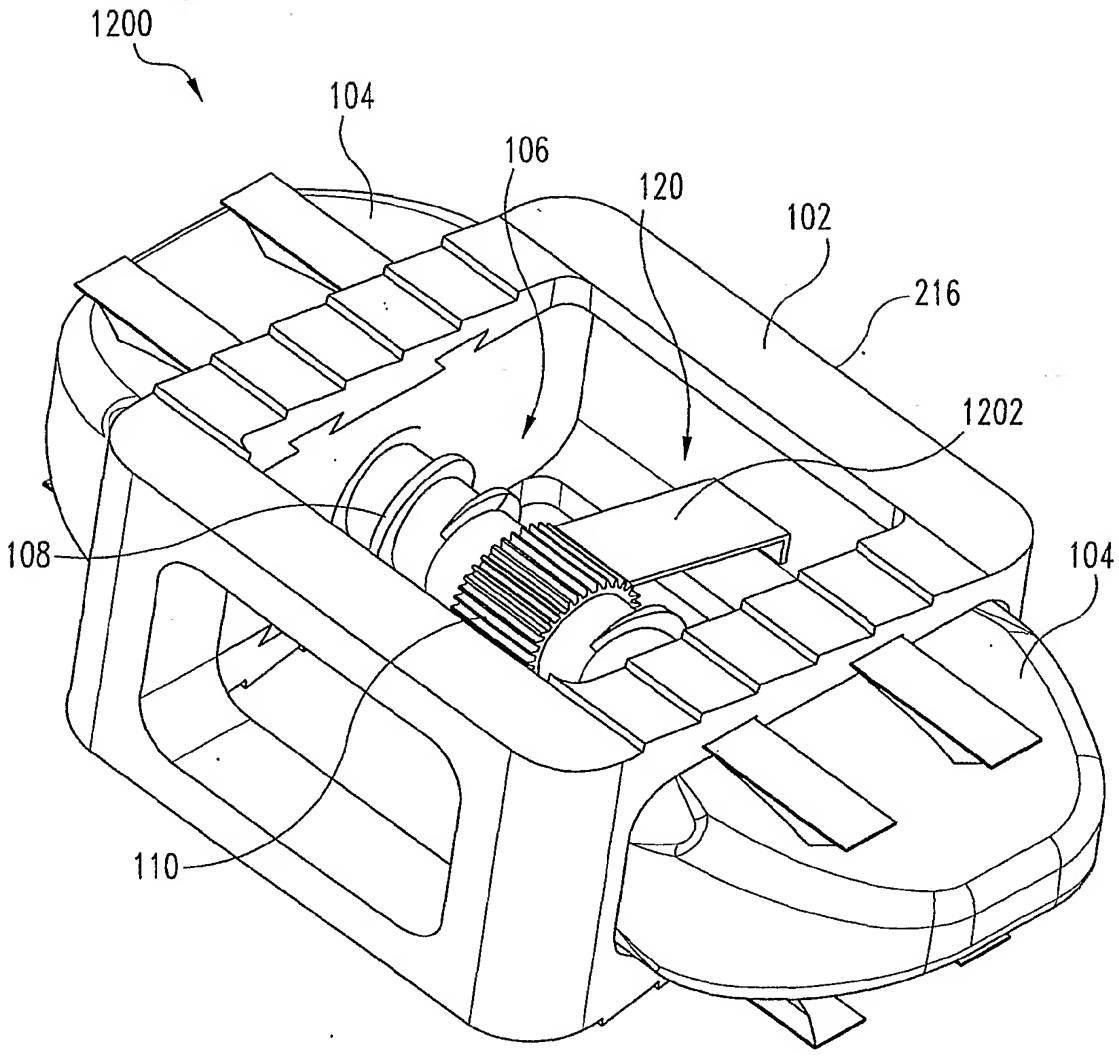

Fig. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US 03/34052

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 6 176 882 B1 (HARMS JUERGEN ET AL) 23 January 2001 (2001-01-23) column 2, line 27 -column 5, line 27; figures 1,7-10	30,31 1,2,4, 13,15, 16,21, 22,28, 32,34
A	US 6 395 031 B1 (EBNER HARALD ET AL) 28 May 2002 (2002-05-28) column 1, line 53 - line 56 column 3, line 66 -column 6, line 55; figures 1-9	1
A	US 6 039 761 A (LI LEHMANN K ET AL) 21 March 2000 (2000-03-21) the whole document	1,30

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 March 2004	24/03/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lickel, A

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/34052

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-29

   A spinal implant comprising a cage defining an interior cavity, an expansion mechanism in said cavity, a pair of wings each having opposing vertebrae engaging surfaces and operatively coupled to said expansion mechanism, whereby said expansion mechanism is operable to laterally move said wings.

2. Claims: 30-31

   A spinal fusion device comprising a central member, at least a pair of lateral members slidably coupled to said central member and means for extending said lateral members from said central member into the disc space.

3. Claims: 32-37

   An apparatus comprising a spinal implant, which comprises a central member defining an interior cavity and a pair of openings on opposite sides of said central member, in which a pair of wings are slidably received, and a shaft having at least one threaded portion threadedly engaging at least one of said wings.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internatio[redacted]Application No
PCT/US 03/34052

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(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété Intellectuelle
Bureau international

(43) Date de la publication internationale
27 mai 2004 (27.05.2004)

PCT

(10) Numéro de publication internationale
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(51) Classification internationale des brevets[7] : A61F 2/44

(21) Numéro de la demande internationale :
PCT/FR2003/003149

(22) Date de dépôt international :
24 octobre 2003 (24.10.2003)

(25) Langue de dépôt : français

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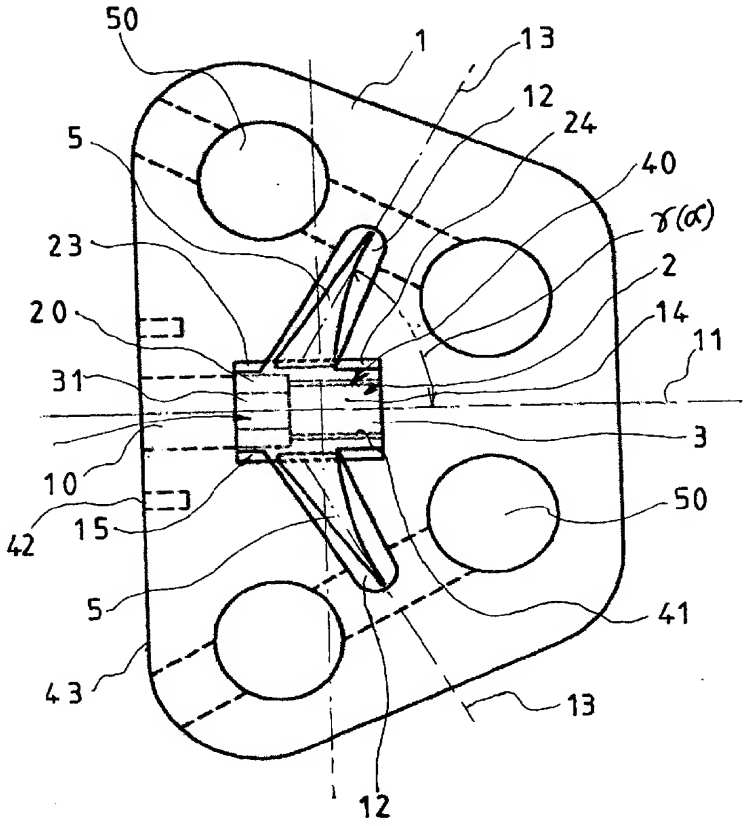
(54) **Title:** INTERVERTEBRAL CAGE WITH MEDIAL FIXING PLATE

(54) **Titre :** CAGE INTERVERTEBRALE A LAME D'ANCRAGE MEDIANE



(57) Abstract: The invention relates to intervertebral cages for the treatment of degenerative spinal conditions. According to the invention, said cage comprises a block (1), a fixing plate (2) with a pivot (3) and two wings (5) attached to said pivot (3), means for mounting the pivot (3) by rotating relative to the block (1), having a hole (10) in the block (1), a slot (12) in the block, said slot (12) embodied such as to have, in common with the hole (10), a common part (14) for housing the pivot (3) and means (15) for connecting the pivot (3) in rotation with the block (1) within the part (14) such that, on rotating the pivot, the fixing plate adopts a first position where the wing (5) is totally enclosed within the slot (12) and a second position in which a part (16) of the end of the wing emerges from the slot.

(57) Abrégé : La présente invention concerne les cages intervertébrales pour le traitement du rachis dégénératif. La cage selon l'invention se caractérise essentiellement par le fait qu'elle comporte un bloc 1, une lame d'ancrage 2 comportant un pivot 3 et deux ailettes 5 solidaires du pivot 3, des moyens pour monter le pivot 3 en rotation par rapport au bloc 1 comportant une percée 10 réalisée dans le bloc 1, une saignée 12 réalisée dans le bloc, cette saignée 12 étant réalisée de façon qu'elle ait, avec la percée 10, une partie commune 14 pour contenir le pivot 3,

[Suite sur la page suivante]

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En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

et des moyens 15 pour associer le pivot 3 en rotation avec le bloc 1 dans la partie 14 de façon que, lorsque le pivot subit une rotation, la lame d'ancrage prenne une première position dans laquelle l'ailette 5 est totalement contenue dans la saignée 12, et une seconde position dans laquelle une portion 16 de l'extrémité de l'ailette émerge de la saignée.

CAGE INTERVERTEBRALE A LAME D'ANCRAGE MEDIANE

La présente invention concerne les cages intervertébrales qui trouvent une application particulièrement avantageuse, mais non exclusivement, pour le traitement du rachis dégénératif, et plus particulièrement un perfectionnement à des cages intervertébrales déjà connues.

En effet, des cages intervertébrales, notamment pour le traitement du rachis dégénératif, sont déjà connues. Une telle cage est par exemple décrite dans le document EP-A-1 104 665. Elle comporte essentiellement une entretoise en forme de disque comprenant deux faces de base opposées sensiblement planes et parallèles et une paroi latérale reliant les deux faces de base. Cette entretoise est apte à être disposée entre les faces en regard des deux corps vertébraux respectivement de deux vertèbres consécutives, en remplacement du disque endommagé situé entre ces deux vertèbres, les deux faces de base de l'entretoise étant placées au contact des corps vertébraux. L'entretoise peut en outre comporter une cavité ouverte dans laquelle il est possible de placer un greffon osseux ou analogue dans le but de souder entre eux les deux corps vertébraux par ostéosynthèse. La cage comprend aussi au moins une lame, comportant deux extrémités opposées conformées en biseau, et des moyens pour déplacer cette lame par rapport à une première des deux parties de paroi latérale de façon que la lame soit apte à prendre deux positions, une première position dans laquelle la lame est entièrement située dans l'espace compris entre les deux premier et second plans contenant les deux faces de base de l'entretoise, et une seconde position dans laquelle les deux extrémités opposées de la lame émergent de part et d'autre de cet espace.

Dans les cages décrites ci-dessus, la lame d'ancrage est associée à une entretoise sur une face de cette dernière. Une telle réalisation nécessite un certain nombre d'éléments pour pouvoir obtenir de façon relativement aisée la rotation de la lame par rapport à l'entretoise. Pour tenter de minimiser le nombre de ces éléments, une solution a été tentée, celle qui consiste à positionner la lame d'ancrage sensiblement dans la partie médiane de l'entretoise, comme par exemple dans le mode de réalisation qui est décrit dans le WO 01/01894. La solution adoptée pour la réalisation de cette cage n'a cependant pas donné entière satisfaction, essentiellement par le fait que l'intégration de la lame dans la

partie médiane de l'entretoise était encore trop complexe et rendait relativement compliquée l'implantation de la cage entre deux vertèbres.

Pour tenter de pallier les inconvénients mentionnés ci-dessus, il a aussi été réalisé une cage intervertébrale comme celle décrite par exemple dans le US-B1-6 371 987. Cette cage répond de façon générale aux exigences des praticiens mais présente encore des inconvénients notamment pour sa réalisation.

La présente invention a donc pour but de réaliser un perfectionnement aux cages intervertébrales du type de celles définies ci-dessus, qui présente une structure plus facile à réaliser et à assembler, et qui permet une implantation beaucoup plus aisée de la cage entre deux vertèbres.

Plus précisément, la présente invention a pour objet une cage intervertébrale pour le traitement du rachis dégénératif apte à être interposée entre deux vertèbres consécutives, comprenant :

• un bloc,

• au moins une lame d'ancrage comportant un pivot définissant un premier axe de rotation, et au moins une ailette montée solidaire dudit pivot suivant sensiblement un premier plan faisant avec ledit premier axe un angle α non nul, et

• des moyens pour monter le pivot en rotation par rapport au dit bloc, comportant une percée réalisée dans le bloc suivant un second axe, une saignée réalisée dans le bloc suivant sensiblement un second plan faisant avec le second axe un angle γ sensiblement égal à l'angle α, la saignée étant en outre réalisée de façon qu'elle ait, avec la percée, une partie commune apte à contenir le pivot, et des moyens pour associer le pivot en rotation avec le bloc quand le pivot est positionné dans ladite partie commune et de façon que lorsque, dans cette position, le pivot subit une rotation d'une amplitude donnée par rapport au bloc, la lame d'ancrage soit apte à prendre au moins deux première et seconde positions, la première position étant celle dans laquelle l'ailette est totalement contenue dans la saignée, et la seconde position étant celle dans laquelle une portion de l'extrémité de l'ailette émerge de ladite saignée,

caractérisée par le fait que, le pivot étant constitué par un second arbre de rotation ayant pour axe le premier axe, les moyens pour associer le pivot en rotation avec le bloc comportent un second palier ouvert en direction de

l'ouverture de ladite saignée située en surface du bloc, ledit second palier ouvert étant réalisé en bordure de ladite partie commune de façon qu'il soit centré sur ledit second axe, les diamètres du second palier ouvert et du second arbre de rotation étant sensiblement égaux, le diamètre du second arbre de rotation et du second palier ouvert étant supérieur à la dimension diamétrale minimale de la section transversale de la percée.

D'autres caractéristiques et avantages de l'invention apparaîtront au cours de la description suivante donnée en regard des dessins annexés à titre illustratif mais nullement limitatif, dans lesquels :

La figure 1 représente une vue en perspective cavalière, en demi-coupe et en éclaté, d'un premier mode de réalisation schématique de la cage intervertébrale selon l'invention,

La figure 2 représente une vue de dessus d'un deuxième mode de réalisation préféré de la cage selon l'invention, et

La figure 3 représente une vue partielle en coupe d'un autre troisième mode de réalisation possible de la cage selon l'invention.

Il est bien précisé que, sur les figures, les mêmes références désignent les mêmes éléments, quelle que soit la figure sur laquelle elles apparaissent et quelle que soit la forme de représentation de ces éléments.

De même, si des éléments ne sont pas spécifiquement référencés sur l'une des figures, leurs références peuvent être aisément retrouvées en se reportant à une autre figure.

Le Demandeur tient aussi à préciser que les figures représentent trois modes de réalisation de l'objet selon l'invention, mais qu'il peut exister d'autres modes de réalisation qui répondent à la définition de cette invention.

Il précise en outre que, lorsque, selon la définition de l'invention, l'objet de l'invention comporte "au moins un" élément ayant une fonction donnée, le mode de réalisation décrit peut comporter plusieurs de ces éléments.

Il précise aussi que, si les modes de réalisation de l'objet selon l'invention tel qu'illustrés comportent plusieurs éléments de fonction identique et que si, dans la description, il n'est pas spécifié que l'objet selon cette invention doit obligatoirement comporter un nombre particulier de ces éléments, l'objet de l'invention pourra être défini comme comportant "au moins un" de ces éléments.

La présente invention concerne une cage intervertébrale perfectionnée pour, notamment, le traitement du rachis dégénératif.

La figure 1, sous forme schématique fonctionnelle, un mode de réalisation d'une cage intervertébrale selon l'invention.

Cette cage comprend un bloc 1 d'une forme assimilable à celle d'un parallélépipède rectangle ou, plus généralement, qui peut être inscrite dans un parallélépipède rectangle. Elle peut notamment être comme celle illustrée sur la figure 2.

La cage comporte aussi au moins une lame d'ancrage 2 comportant un pivot 3 définissant un premier axe de rotation 4, et au moins une ailette 5 montée solidaire du pivot 3 suivant sensiblement un premier plan 6 faisant avec le premier axe 4 un angle α non nul, et avantageusement deux ailettes comme dans les réalisations selon les figures 2 et 3 pour s'ancrer dans les deux vertèbres consécutives entre lesquelles la cage est destinée à être implantée.

Elle comporte des moyens pour monter le pivot 3 en rotation par rapport au bloc 1, qui comprennent une percée 10 réalisée dans le bloc suivant un second axe 11, une saignée 12 réalisée dans le bloc suivant sensiblement un second plan 13 faisant avec le second axe 11 un angle γ sensiblement égal à l'angle α, la saignée 12 étant en outre réalisée de façon qu'elle ait, avec la percée 10, une partie commune 14 apte à contenir le pivot 3, et des moyens 15 pour associer le pivot 3 en rotation avec le bloc 1 quand le pivot est positionné dans la partie commune 14 et de façon que lorsque, dans cette position, le pivot subit une rotation d'une amplitude donnée par rapport au bloc, la lame d'ancrage 2 soit apte à prendre au moins deux première et seconde positions, la première position étant celle dans laquelle l'ailette 5 est totalement contenue dans la saignée 12, et la seconde position étant celle dans laquelle une portion 16 de l'extrémité de l'ailette émerge de la saignée.

Il est précisé que, dans le mode de réalisation selon la figure 1, la lame d'ancrage 2 ne comporte qu'une ailette 5. Dans ce cas, la saignée 12 peut avoir la forme telle qu'illustrée sur cette figure 1. Dans le cas où la lame d'ancrage comporte deux ailettes sensiblement symétriques, comme dans le mode de réalisation selon la figure 2, à chaque ailette correspond au moins une saignée 12 comme celle illustrée sur la figure 1. Cependant, dans un mode de réalisation

avantageux notamment sur le plan de l'usinage, les deux saignées correspondant aux deux ailettes seront réalisées suivant une seule saignée traversant de part en part le bloc 1 comme illustré sur la figure 2, cette réalisation permettant en outre de faire pivoter la lame d'ancrage dans un sens ou dans l'autre pour obtenir les résultats définis ci-après.

Dans le mode de réalisation illustré sur la figure 1, les angles α et γ sont sensiblement égaux à 90 degrés mais ils seront avantageusement choisis à une valeur inférieure, par exemple 70 degrés pour permettre un accrochage rétentif de la cage avec les deux vertèbres.

Dans une réalisation possible comme celle illustrée sur la figure 3, le pivot 3 est constitué par un premier palier en creux 17, avantageusement en forme de manchon dont la paroi intérieure est cylindrique de révolution. Dans ce cas, les moyens 15 pour associer le pivot 3 en rotation avec le bloc 1 comportent un premier arbre de rotation 18 monté avec des moyens d'indexation en rotation dans le premier palier en creux 17, et des moyens 19 pour monter le premier arbre de rotation 18 en coopération avec le bloc 1. Comme illustré sur la figure 3, ces moyens 19 peuvent être constitués par un assemblage du type à clavette par exemple solidaire du pivot 3 coopérant avec une rainure correspondante réalisée dans le premier arbre de rotation 18. De plus, ce premier arbre de rotation 18 a une section transversale sensiblement complémentaire de celle de la percée 10 pour qu'il puisse y être introduit à friction relativement dure.

Ce mode de réalisation est relativement intéressant sur le plan de sa structure et pour l'implantation de la cage.

Cependant, à ce mode de réalisation selon la figure 3, est préféré un mode de réalisation comme celui illustré sur les figures 1 et 2, qui présente deux avantages essentiels par rapport au mode de réalisation selon la figure 3, à savoir qu'il nécessite moins d'éléments constitutifs, deux au lieu de trois, que l'assemblage de ces éléments se fait très facilement, automatiquement.

Dans les modes de réalisation selon les figures 1 et 2, le pivot 3 est constitué par un second arbre de rotation 20 ayant pour axe le premier axe 4, et les moyens 15 pour associer le pivot en rotation avec le bloc comportent un second palier 21 ouvert en direction de l'ouverture 22 de la saignée 12 située en surface du bloc 1, le second palier ouvert étant réalisé en bordure de la partie

commune 14 de façon qu'il soit centré sur le second axe 11, les diamètres du second palier ouvert 21 et du second arbre de rotation 20 étant sensiblement égaux.

Avantageusement, le diamètre du second arbre de rotation 20 et du second palier ouvert 21 est supérieur à la dimension diamétrale minimale de la section transversale de la percée 10. De cette façon, quand le pivot est disposé dans le second palier ouvert 21, il est maintenu entre les deux épaulements formés par le bord 28 de l'extrémité de la percée 10 qui débouche dans la partie commune 14 et par la paroi 29 de la saignée 12.

De façon préférentielle, le second palier ouvert 21 est constitué de deux surfaces cylindriques ouvertes 23, 24 séparées par un espace libre 25 d'une largeur au moins égale à l'épaisseur maximale de l'ailette 5 prise au niveau de sa partie 26 qui est solidaire du pivot 3.

Dans un mode de réalisation avantageux, ce second palier ouvert 21 est un palier de rétention. Dans ce cas, au moins l'une des deux surfaces cylindriques ouvertes 23, 24, et avantageusement les deux, est définie sur un angle supérieur à 180 degrés, mais cependant très peu supérieur à 180 degrés.

De plus, selon le mode de réalisation décrit ci-dessus, les deux surfaces cylindriques ouvertes 23, 24 sont reliées à la surface du bloc 1 sur laquelle débouche la saignée 12, respectivement par deux rampes 33, 34 qui forment deux rampes de guidage pour l'introduction du second arbre de rotation 20 dans le second palier en creux 21. Sur la figure 1, ces deux rampes 33, 34, que l'on retrouve bien entendu de façon symétrique dans l'autre moitié du bloc 1 non représentée, forment un entonnoir dont l'angle au sommet est relativement grand afin de faire ressortir la fonction de guidage de ces deux rampes. Cependant, dans la pratique, comme illustré sur la figure 1, cet angle au sommet a une valeur très faible.

La cage intervertébrale comporte en outre des moyens 30 pour entraîner en rotation le pivot 3 autour du second axe 11 de façon que la lame d'ancrage 2 soit apte à prendre ses deux première et seconde positions définies ci-avant.

Ces moyens 30 sont par exemple constitués d'un logement en creux 31 à section transversale polygonale réalisé dans la face 32 du second arbre de rotation 20 qui est en regard de la percée 10 quand le second arbre de rotation 20 est monté en rotation dans le second palier ouvert 21, ce logement en creux 31

étant sensiblement centré sur le premier axe 4 et ayant une section transversale inférieure à celle de la percée 10.

Dans une réalisation avantageuse, la cage intervertébrale comporte un orifice 40 dans la paroi duquel est réalisé un taraudage 41, qui est réalisé dans le second arbre de rotation 20 en étant centré sur le premier axe 4 et en débouchant dans le fond du logement en creux 31, le diamètre de l'orifice taraudé 40 étant inférieur à la section transversale de ce logement en creux, et des moyens 42 pour indexer la position d'un ancillaire par rapport au bloc 1 réalisés sur la face 43 du bloc sur laquelle débouche la percée 10. Ces moyens 42 sont par exemple constitués de deux encoches, ou plus, en sachant que l'ancillaire doit comporter des ergots aptes à être enfichés dans les encoches 42 et une tige filetée apte à se visser dans l'orifice taraudé 40 lorsque les ergots sont enfichés dans les encoches.

Les éléments de la cage intervertébrale telle que décrite ci-dessus en regard plus particulièrement des figures 1 et 2 s'assemblent comme suit et la cage s'utilise de la façon suivante :

Tout d'abord, il est précisé que le bloc 1 et la lame d'ancrage 2 sont usinés de façon classique pour avoir les caractéristiques structurelles décrites ci-avant. Ces deux éléments étant réalisés, la lame d'ancrage 2 est présentée, par le pivot 20, dans l'entonnoir formé par les rampes 33, 34. Elle est poussée en force jusqu'à ce que le pivot vienne s'encliqueter dans le second palier ouvert 21. Dès que le pivot est positionné dans ce second palier ouvert, il y est parfaitement maintenu par les deux épaulements 28, 29 et par les deux surfaces cylindriques ouvertes 23, 24 définies sur un angle supérieur à 180 degrés.

Lorsque la lame d'ancrage 2 a pris une position comme celle illustrée en traits interrompus sur la figure 1, qui correspond à sa seconde position définie auparavant, au moyen par exemple d'une clé à section polygonale Cp, représentée en traits interrompus sur la figure 1, complémentaire du logement 31 introduite dans ce logement via la percée 10, la lame d'ancrage 2 est amenée dans sa première position comme représentée sur la figure 2. Dans cette position, les deux ailettes 5 de la lame sont complètement escamotées, entièrement contenues dans les saignées 12.

De façon connue, le praticien introduit alors la cage selon l'invention entre deux vertèbres consécutives en remplacement du disque intervertébral, la lame

d'ancrage étant dans sa première position. Pour ce faire, le praticien utilise l'ancillaire décrit ci-avant.

Au moyen de la clé à section polygonale Cp introduite dans le logement 31 via la percée 10, le praticien fait alors passer la lame d'ancrage de sa première position à sa seconde position, les portions d'extrémité 16 des ailettes 5 s'implantant dans les parties osseuses des deux vertèbres, de la même façon que dans le cas des cages intervertébrales du même type selon l'art antérieur.

Pour déterminer la seconde position de la lame d'ancrage et favoriser la pose de la cage par le praticien, la cage peut comporter en outre, par exemple un premier cliquet constitué de façon connue en elle-même d'un ergot réalisé sur le pivot et d'une rainure réalisée dans le bloc 1 qui coopèrent l'un dans l'autre, par exemple par déformation, quand la lame d'ancrage arrive dans sa seconde position. La cage peut aussi comporter un second cliquet pour définir la première position de la lame d'ancrage, le même ergot pouvant d'ailleurs être commun aux deux cliquets.

Il est précisé que la cage selon l'invention peut comporter en outre d'autres caractéristiques que celles définies ci-dessus, par exemple des trous 50 de réception de greffons osseux, comme représenté sur la figure 2. Ces autres caractéristiques n'ont pas été décrites ici car elles n'entrent pas dans le champ de la présente invention.

REVENDICATIONS

1. Cage intervertébrale pour le traitement du rachis dégénératif apte à être interposée entre deux vertèbres consécutives, comprenant :

• un bloc (1),

• au moins une lame d'ancrage (2) comportant un pivot (3) définissant un premier axe de rotation (4), et au moins une ailette (5) montée solidaire dudit pivot (3) suivant sensiblement un premier plan (6) faisant avec ledit premier axe (4) un angle α non nul, et

• des moyens pour monter le pivot (3) en rotation par rapport au dit bloc (1), comportant une percée (10) réalisée dans le bloc (1) suivant un second axe (11), une saignée (12) réalisée dans le bloc suivant sensiblement un second plan (13) faisant avec le second axe (11) un angle γ sensiblement égal à l'angle α, la saignée (12) étant en outre réalisée de façon qu'elle ait, avec la percée (10), une partie commune (14) apte à contenir le pivot (3), et des moyens (15) pour associer le pivot (3) en rotation avec le bloc (1) quand le pivot est positionné dans ladite partie commune (14) et de façon que lorsque, dans cette position, le pivot subit une rotation d'une amplitude donnée par rapport au bloc, la lame d'ancrage (2) soit apte à prendre au moins deux première et seconde positions, la première position étant celle dans laquelle l'ailette (5) est totalement contenue dans la saignée (12), et la seconde position étant celle dans laquelle une portion (16) de l'extrémité de l'ailette émerge de ladite saignée,

caractérisée par le fait que, le pivot (3) étant constitué par un second arbre de rotation (20) ayant pour axe le premier axe (4), les moyens (15) pour associer le pivot en rotation avec le bloc comportent un second palier (21) ouvert en direction de l'ouverture (22) de ladite saignée (12) située en surface du bloc (1), ledit second palier ouvert étant réalisé en bordure de ladite partie commune (14) de façon qu'il soit centré sur ledit second axe (11), les diamètres du second palier ouvert (21) et du second arbre de rotation (20) étant sensiblement égaux, le diamètre du second arbre de rotation (20) et du second palier ouvert (21) étant supérieur à la dimension diamétrale minimale de la section transversale de la percée (10).

2. Cage intervertébrale selon la revendication 1, caractérisée par le fait que le second palier ouvert (21) est constitué de deux surfaces cylindriques ouvertes (23, 24) séparées par un espace libre (25) d'une largeur au moins égale à l'épaisseur maximale de l'ailette (5) prise au niveau de sa partie (26) qui est solidaire du pivot (3).

3. Cage intervertébrale selon la revendication 2, caractérisée par le fait que le second palier ouvert (21) est un palier de rétention.

4. Cage intervertébrale selon la revendication 3, caractérisée par le fait qu'au moins l'une des deux surfaces cylindriques ouvertes (23, 24) est définie sur un angle supérieur à 180 degrés.

5. Cage intervertébrale selon l'une des revendications 1 à 4, caractérisée par le fait qu'elle comporte des moyens (30) pour entraîner en rotation ledit pivot (3) autour dudit second axe (11) de façon que ladite lame d'ancrage (2) soit apte à prendre ses deux dites première et seconde positions.

6. Cage intervertébrale selon la revendication 5, caractérisée par le fait que les moyens (30) pour entraîner en rotation ledit pivot (3) autour dudit second axe (11) comportent un logement en creux (31) à section transversale polygonale réalisé dans la face (32) du second arbre de rotation (20) qui est en regard de la percée (10) quand ledit second arbre de rotation (20) est monté en rotation dans le second palier ouvert (21), ledit logement en creux (31) étant sensiblement centré sur ledit premier axe (4) et ayant une section transversale inférieure à celle de ladite percée (10).

7. Cage intervertébrale selon la revendication 6, caractérisée par le fait qu'elle comporte un orifice (40) comportant un taraudage (41), ledit orifice étant réalisé dans le second arbre de rotation (20) en étant centré sur le premier axe (4) et en débouchant dans le fond dudit logement en creux (31), le diamètre dudit orifice taraudé (40) étant inférieur à la section transversale dudit logement en creux (31), et des moyens (42) pour indexer la position d'un ancillaire par rapport

au bloc (1) réalisés sur la face (43) du bloc sur laquelle débouche ladite percée (10).

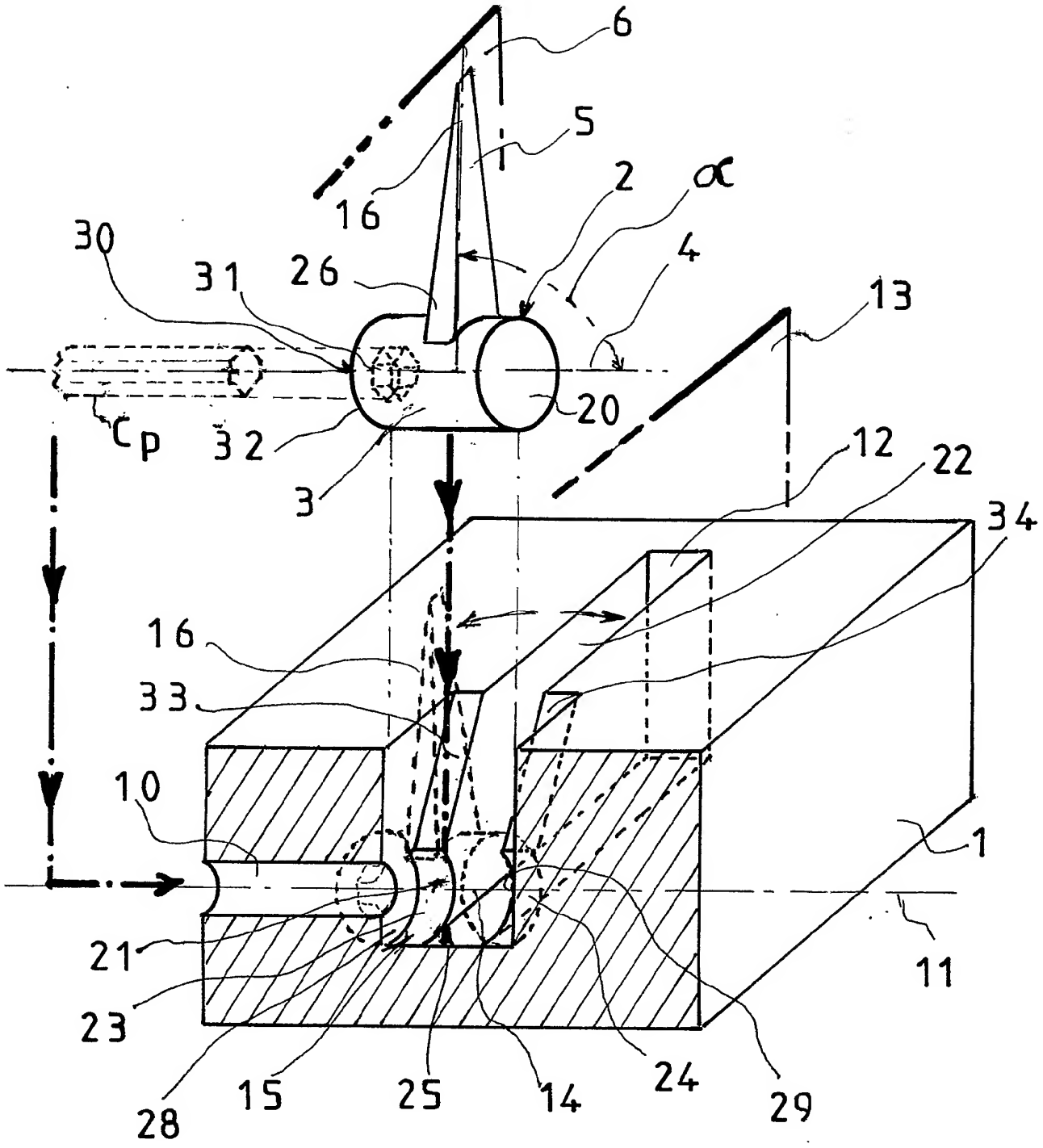
8. Cage intervertébrale pour le traitement du rachis dégénératif apte à être interposée entre deux vertèbres consécutives, comprenant :

• un bloc (1),

• au moins une lame d'ancrage (2) comportant un pivot (3) définissant un premier axe de rotation (4), et au moins une ailette (5) montée solidaire dudit pivot (3) suivant sensiblement un premier plan (6) faisant avec ledit premier axe (4) un angle α non nul, et

• des moyens pour monter le pivot (3) en rotation par rapport au dit bloc (1), comportant une percée (10) réalisée dans le bloc (1) suivant un second axe (11), une saignée (12) réalisée dans le bloc suivant sensiblement un second plan (13) faisant avec le second axe (11) un angle γ sensiblement égal à l'angle α, la saignée (12) étant en outre réalisée de façon qu'elle ait, avec la percée (10), une partie commune (14) apte à contenir le pivot (3), et des moyens (15) pour associer le pivot (3) en rotation avec le bloc (1) quand le pivot est positionné dans ladite partie commune (14) et de façon que lorsque, dans cette position, le pivot subit une rotation d'une amplitude donnée par rapport au bloc, la lame d'ancrage (2) soit apte à prendre au moins deux première et seconde positions, la première position étant celle dans laquelle l'ailette (5) est totalement contenue dans la saignée (12), et la seconde position étant celle dans laquelle une portion (16) de l'extrémité de l'ailette émerge de ladite saignée,

caractérisée par le fait que, le pivot (3) étant constitué par un premier palier en creux (17), les moyens (15) pour associer le pivot (3) en rotation avec le bloc (1) comportent un premier arbre de rotation (18) monté avec des moyens d'indexation en rotation dans ledit premier palier en creux (17), et des moyens (19) pour monter ledit premier arbre de rotation (18) en coopération avec ledit bloc (1).


6
5
16
2
α
4
30
31
26
13
20
Cp
32
3
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33
10
1
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28
15
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fig. 1

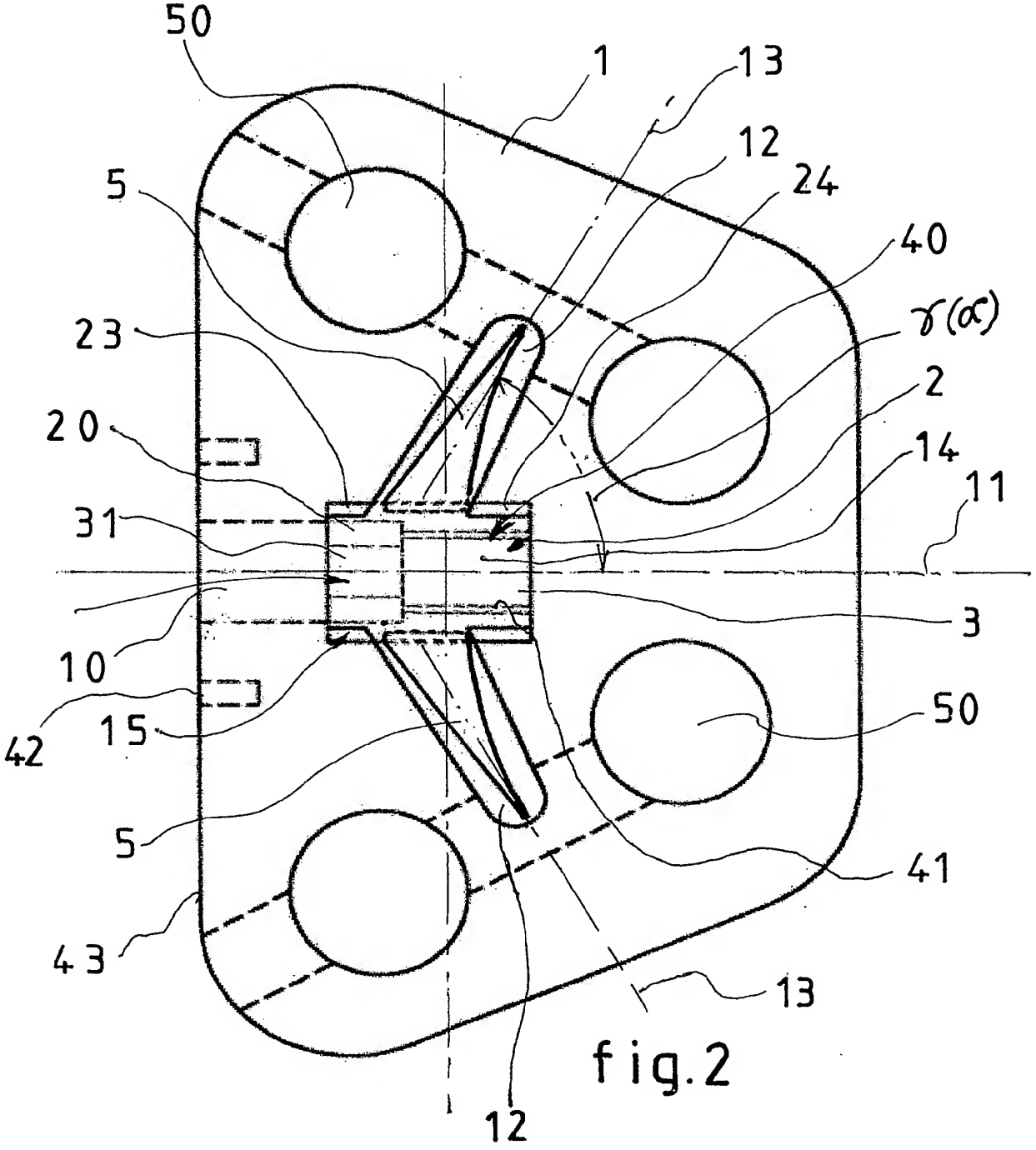

fig.2

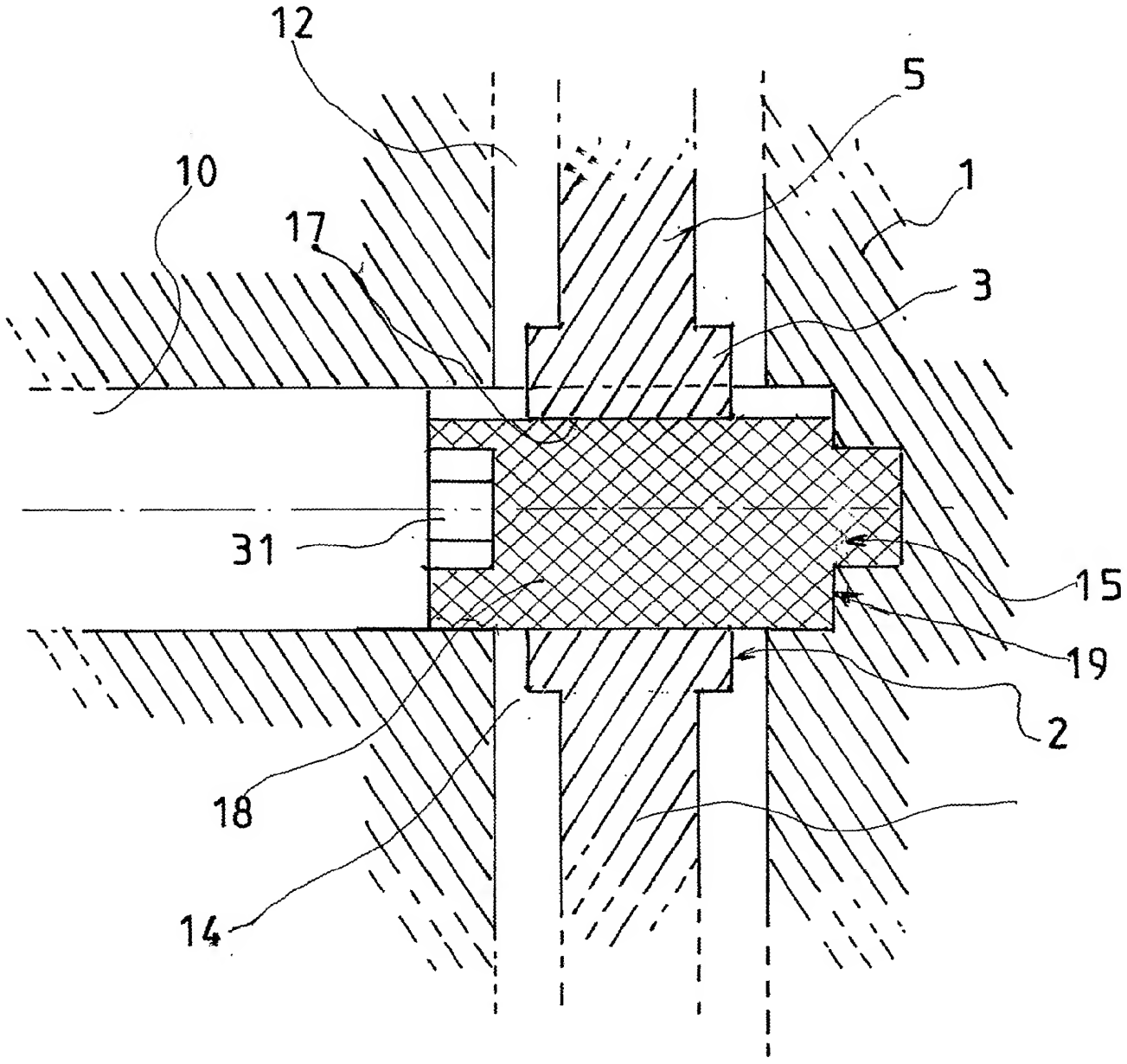

fig. 3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/FR 03/03149

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 371 987 B1 (WEILAND PETER ET AL) 16 April 2002 (2002-04-16) column 2, line 20 -column 3, line 3 column 4, line 60 -column 5, line 23	1-8
A	DE 198 16 832 C (AESCULAP AG & CO KG) 20 January 2000 (2000-01-20) column 5, line 8 - line 32	1-8
A	US 5 683 394 A (RINNER JAMES A) 4 November 1997 (1997-11-04) the whole document	1-8
A	US 6 102 949 A (HARMS JUERGEN ET AL) 15 August 2000 (2000-08-15) the whole document	1-8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 March 2004	06/04/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Buchmann, G

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/FR 03/03149

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6371987 B1	16-04-2002	DE 19818143 A1	28-10-1999
		EP 0951879 A2	27-10-1999
		JP 11347056 A	21-12-1999
DE 19816832 C	20-01-2000	DE 29806833 U1	25-06-1998
		DE 19816832 C1	20-01-2000
US 5683394 A	04-11-1997	NONE	
US 6102949 A	15-08-2000	CH 693353 A5	30-06-2003
		DE 19753685 C1	16-09-1999
		FR 2787020 A1	16-06-2000

RAPPORT DE RECHERCHE INTERNATIONALE

Demande Internationale No
PCT/FR 03/03149

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 7 A61F2/44

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 7 A61F

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)
EPO-Internal

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie °	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	US 6 371 987 B1 (WEILAND PETER ET AL) 16 avril 2002 (2002-04-16) colonne 2, ligne 20 -colonne 3, ligne 3 colonne 4, ligne 60 -colonne 5, ligne 23	1-8
A	DE 198 16 832 C (AESCULAP AG & CO KG) 20 janvier 2000 (2000-01-20) colonne 5, ligne 8 - ligne 32	1-8
A	US 5 683 394 A (RINNER JAMES A) 4 novembre 1997 (1997-11-04) le document en entier	1-8
A	US 6 102 949 A (HARMS JUERGEN ET AL) 15 août 2000 (2000-08-15) le document en entier	1-8

☐ Voir la suite du cadre C pour la fin de la liste des documents

☒ Les documents de familles de brevets sont indiqués en annexe

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"X" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive par rapport au document considéré isolément

"Y" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier

"&" document qui fait partie de la même famille de brevets

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
26 mars 2004	06/04/2004

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Buchmann, G

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale No
PCT/FR 03/03149

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
US 6371987	B1	16-04-2002	DE	19818143 A1	28-10-1999
			EP	0951879 A2	27-10-1999
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DE 19816832	C	20-01-2000	DE	29806833 U1	25-06-1998
			DE	19816832 C1	20-01-2000
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US 6102949	A	15-08-2000	CH	693353 A5	30-06-2003
			DE	19753685 C1	16-09-1999
			FR	2787020 A1	16-06-2000

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

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Internationales Büro

(43) Internationales Veröffentlichungsdatum
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WO 2004/052245 A1

(51) Internationale Patentklassifikation[7]: A61F 2/44

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6. Dezember 2002 (06.12.2002)

(25) Einreichungssprache: Deutsch

(26) Veröffentlichungssprache: Deutsch

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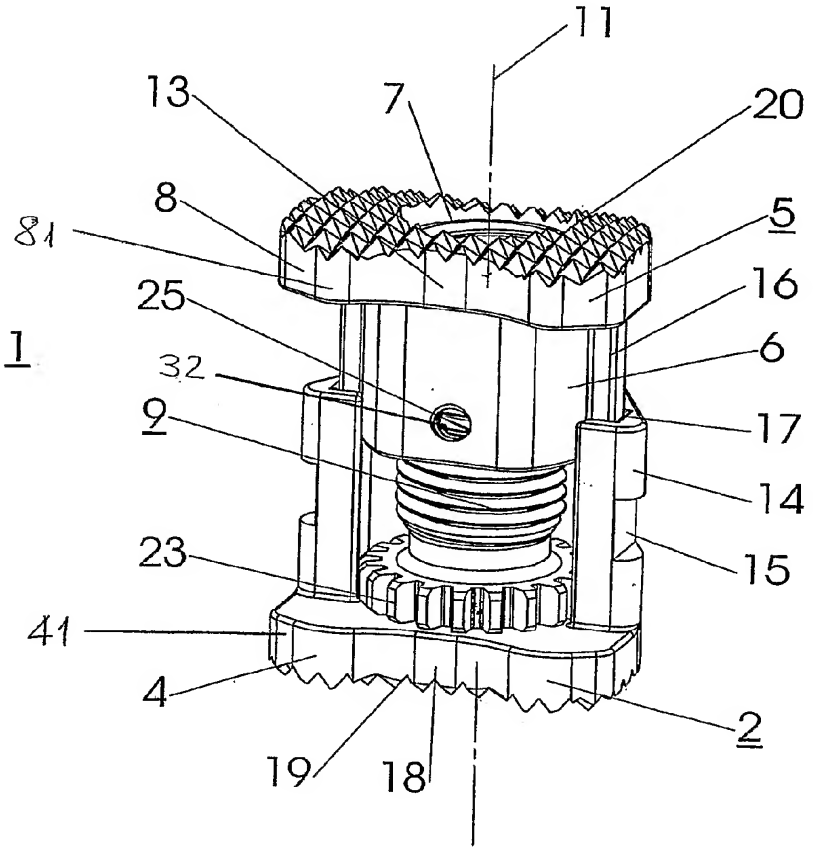
(81) Bestimmungsstaaten *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR,

[Fortsetzung auf der nächsten Seite]

(54) Title: INTERVERTEBRAL IMPLANT

(54) Bezeichnung: ZWISCHENWIRBELIMPLANTAT



(57) Abstract: The invention relates to an intervertebral implant (1) comprising a lower implant part (2), which comprises a central axis (11) and an apposition section (4), designed to rest against the covering surface of the adjacent lower vertebra and an upper implant part (5) comprising a bore (30) with an internal thread (7), a central axis (11) and an apposition section (8), designed to rest against the covering surface of the adjacent upper vertebra. The invention is characterised in that the two implant parts (2, 5) are secured in relation to each other against rotation about the central axis (11) and that a threaded screw (9) with an external thread (10) is guided in the upper implant part (5) and connected to the lower implant part (2), said external thread co-operating with the internal thread (7). The two implant parts (2, 5) and the threaded screw (9) lie coaxially along their common central axis (11), said threaded screw (9) being connected to the lower implant part (2) so that it is axially fixed but able to rotate.

[Fortsetzung auf der nächsten Seite]

WO 2004/052245 A1

CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Bestimmungsstaaten *(regional)*: ARIPO-Patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI-Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Veröffentlicht:

— *mit internationalem Recherchenbericht*

— *mit geänderten Ansprüchen*

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

(57) Zusammenfassung: 1. Zwischenwirbelimplantat (1) mit A) einem unteren Implantatteil (2), welches eine Zentralachse (11) und einen zur Anlage an die Deckfläche des angrenzenden unteren Wirbels bestimmten Appositionsteil (4) umfasst; B) einem oberen Implantatteil (5) mit einer ein Innengewinde (7) aufweisenden Bohrung (30) und Zentralachse (11) und einem zur Anlage an die Deckfläche des angrenzenden oberen Wirbels bestimmten Appositionsteil (8); wobei C) die beiden Implantatteile (2, 5) relativ zueinander gegen Rotation um die Zentralachse (11) gesichert sind; sowie D) einer im oberen Implantatteil (5) geführten und mit dem unteren Implantatteil (2) verbundenen Gewindespindel (9) mit Aussengewinde (10), welches mit dem Innengewinde (7) zusammenwirkt; wobei E) die beiden Implantatteile (2, 5) und die Gewindespindel (9) koaxial längs ihrer gemeinsamen Zentralachse (11) angeordnet sind, wobei F) die Gewindespindel (9) axial fest aber rotativ beweglich mit dem unteren Implantatteil (2) verbunden ist.

Zwischenwirbelimplantat

Die Erfindung bezieht sich auf ein Zwischenwirbelimplantat gemäss dem Oberbegriff des Patentanspruchs 1.

Aus der US-A 2002082695 NEUMANN ist ein gattungsgemässes Zwischenwirbelimplantat bekannt. Dabei ist der mittlere, als Gewindering mit Innengewinde ausgebildete Implantatteil mit dem oberen, endständigen Implantatteil verbunden. Der obere Teil des unteren Implantatteils ist mit einer konischen Fläche ausgestaltet, welche als Aufnahme für den Gewindering dient. Mittels eines speziellen Instrumentes, welches ein mit dem Kegelrad an dem Gewindering in Eingriff bringbares Kegelrad ausweist, kann der Gewindering um die Zentralachse des Zwischenwirbelimplantates rotiert werden und obere Implantatteil axial verschoben werden. Der Gewindering dient dem oberen Implantatteil nur als axialer Anschlag, d.h. als Abstützfläche, so dass das obere, endständige Implantatteil axial bewegt werden kann (Mutter/Spindel-Antrieb). Die beiden endständigen Implantatteile sind somit lose gegeneinander montiert, was sich auch darin zeigt, dass zu ihrer axialer Sicherung axiale Schlitze in einem der beiden Implantatteile vorgesehen ist, in welche am anderen Implantatteil angebrachte Stifte eingreifen. Somit hat dieses bekannte Zwischenwirbelimplantat den Nachteil, dass es prä- und intraoperativ gegen axiale Verschiebungen ungesichert ist .

Hier will die Erfindung Abhilfe schaffen. Der Erfindung liegt die Aufgabe zugrunde, ein Zwischenwirbelimplantat zu schaffen, welches unter Beibehaltung einer geringstmöglichen Bauhöhe ein kompaktes, axial spielfreies Ganzes bildet und als vormontiertes Set dem Chirurgen zur Verfügung gestellt werden kann.

Die Erfindung löst die gestellte Aufgabe mit ein Zwischenwirbelimplantat, welches die Merkmale des Anspruchs 1 aufweist.

Die durch die Erfindung erreichten Vorteile sind im wesentlichen darin zu sehen, dass dank des erfindungsgemässen Zwischenwirbelimplantates ein vereinfachtes Handling möglich ist, da das Einbringen des Implantates durch dessen Distrahierbarkeit und ein

einfaches Instrumentarium sehr schnell geht. Dadurch wird einerseits die Sicherheit erhöht und anderseits der Zeitaufwand für die Implantation reduziert. Durch Verdrehen der Gewindespindel auf dem Innengewinde ist der Abstand zwischen den beiden Appositionsteilen stufenlos veränderbar.

In einer bevorzugten Ausführungsform ist die Gewindespindel mittels einer Klippverbindung am unteren Implantatteil axial fest aber rotativ beweglich befestigt. Diese Klippverbindung wird vorzugsweise durch einen torusförmigen Hinterschnitt am unteren Ende der Gewindespindel und einen damit korrespondierenden ringförmigen Wulst in einer Bohrung im unteren Implantatteil gebildet. Damit ist gewährleistet, dass die beiden Implantatteile durch die Gewindespindel axial zusammengehalten werden. Die Gewindespindel weist vorzugsweise eine untere, auf dem unteren Implantatteil aufliegende und senkrecht zur Zentralachse stehende Fläche auf.

In einer anderen Ausführungsform umfasst die Gewindespindel einen Zahnkranz, welcher vorzugsweise an das untere Implantatteil angrenzt. Der Zahnkranz dient zur rotativen Bewegung der Gewindespindel mittels eines anterior anbringbaren Instrumentes.

In einer weiteren Ausführungsform umfasst der untere Implantatteil eine posteriore, hohlzylindrische Kavität mit einem Mantel. Der Mantel ist vorzugsweise anterior offen.

In wiederum einer weiteren Ausführungsform umfasst der obere Implantatteil einen im wesentlichen kreiszylindrischen Schaft, welcher von der Bohrung mit Innengewinde axial durchdrungen wird.

Vorzugsweise ist der Mantel des unteren Implantatteiles mit zwei senkrecht zur Zentralachse stehenden Schlitze versehen. Diese Schlitze sind lateral am Zwischenwirbelimplantat angebracht und dienen dazu, ein Instrument gegenüber dem Zahnkranz zu positionieren und abzustützten.

In wiederum einer anderen Ausführungsform ist eine Sicherung gegen Rotation des oberen Implantatteils gegenüber dem unteren Implantatteil vorgesehen. Diese Sicherung besteht darin, dass der kreiszylindrische Schaft des oberen Implantatteils

mindestens einen, vorzugsweise jedoch zwei parallel zur Zentralachse und seitlich angebrachte Keile aufweist und der Mantel des unteren Implantatteils an seiner Innenseite mindestens einen, vorzugsweise jedoch zwei seitlich angebrachte Führungsschlitze aufweist. Die Keile sind in den Führungsschlitzen axial verschiebbar, verhindern jedoch eine Rotation der beiden Implantatteile relativ zueinander.

In einer weiteren Ausführungsform ist der kreiszylindrische Schaft derart ausgebildet, dass er einen geringeren Durchmesser aufweist als die Kavität, so dass sich die beiden Bauteile nur durch die beiden Keile in den Führungsschlitzen berühren.

In wiederum einer weiteren Ausführungsform sind das Innengewinde in der Bohrung des kreiszylindrischen Schaftes und das Aussengewinde der Gewindespindel selbsthemmend ausgebildet. Der Vorteil dieser Ausführungsform besteht darin, dass durch die Selbsthemmung des Gewindes das Implantat auf eine beliebige Höhe distrahiert werden kann und ohne zusätzliche Arretierung in dieser Position gehalten werden kann.

Die Steigung des Innengewindes in der Bohrung im Schaft und des Aussengewindes an der Gewindespindel liegt im Bereich von 0,5 bis 1,0 mm, vorzugsweise von 0,6 – 0,8 mm.

Vorzugsweise sind sowohl das Innengewinde als auch das Aussengewinde als Rechtsgewinde ausgebildet. Damit ist der Vorteil erreichbar, dass das Instrument, das das Ritzel trägt, in üblicher Weise, wie ein normaler Schraubenzieher im Uhrzeigersinn gedreht werden kann, um das Implantat zu distrahieren.

In einer anderen Ausführungsform sind in den anterioren Seitenflächen der beiden Appositionsteile zwei kreisförmige Ausnahmen angebracht, welche zur Anlagerung von Stoffen, welche die Fusion unterstützen, beispielsweise Spongiosa geeignet sind.

In wiederum einer anderen Ausführungsform sind die beiden Appositionsteile als quer zur Zentralachse stehende, plattenförmige Elemente mit einer zur Anlage an die Deckfläche des angrenzenden Wirbels bestimmten Appositionsfläche ausgebildet.

In einer weiteren Ausführungsform sind die Appositionsflächen nicht orthogonal zur Zentralachse angeordnet und schliessen vorzugsweise einen Winkel von 80° bis 89 ° mit der Zentralachse ein. Die Deckplatten der Wirbelkörper verlaufen in sagittaler Richtung nicht orthogonal zur Wirbelsäulenachse, sondern weisen dazu einen spitzen Winkel auf. Die Abwinkelung der Appositionsflächen berücksichtigt diese anatomische Gegebenheit.

Vorzugsweise schliessen die beiden Appositionsflächen einen Winkel von 2° bis 20° untereinander ein.

In wiederum einer weiteren Ausführungsform weist mindestens eine der beiden Appositionsflächen, vorzugsweise diejenige des oberen Implantatteils eine in sagittaler Richtung vorliegende Wölbung auf. Der Vorteil dieser Ausführungsform liegt der optimalen Anpassung der Appositionsfächen an die Wirbelkörper.

In wiederum einer weiteren Ausführungsform weist mindestens eine der beiden Appositionsflächen eine in koronaler Richtung vorliegende Wölbung auf. Der Vorteil dieser Ausführungsform liegt in der optimalen Anpassung der Appositionsflächen an die Wirbelkörper.

In einer anderen Ausführungsform ist im Schaft quer zur Zentralachse eine Bohrung mit Gewinde angebracht, in welche eine Stellschraube schraubbar ist. Die Stellschraube dient zur Rotationssicherung der Gewindespindel um die Zentralachse.

In wiederum einer anderen Ausführungsform ist das Zwischenwirbelimplantat mindestens teilweise aus einem röntgenstrahlendurchlässigen Material, vorzugsweise aus PEEK gefertigt. Damit ist der Vorteil erreichbar, dass die Fusion postoperativ besser beurteilbar ist.

Die Erfindung und Weiterbildungen der Erfindung werden im folgenden anhand der teilweise schematischen Darstellungen mehrerer Ausführungsbeispiele noch näher erläutert.

Es zeigen:

Fig. 1 eine perspektivische Ansicht einer Ausführungsform des erfindungsgemässen Zwischenwirbelimplantates;

Fig. 2 eine Explosionsdarstellung der in Fig. 1 dargestellten Ausführungsform des erfindungsgemässen Zwischenwirbelimplantates;

Fig. 3 einen Längsschnitt parallel zur Zentralachse durch die in den Fig. 1 und 2 dargestellte Ausführungsform des erfindungsgemässen Zwischenwirbelimplantates;

Fig. 4 eine Ansicht von anterior der in den Fig. 1 bis 3 dargestellten Ausführungsform des erfindungsgemässen Zwischenwirbelimplantates;

Fig. 5 einen Schnitt parallel zur Zentralachse einer Explosionsdarstellung der in den Fig. 1 bis 4 dargestellten Ausführungsform des erfindungsgemässen Zwischenwirbelimplantates; und

Fig. 6 ein Explosionsdarstellung der in den Fig. 1 bis 5 dargestellten Ausführungsform des erfindungsgemässen Zwischenwirbelimplantates.

In den Fig. 1 bis 6 ist eine Ausführungsform des erfindungsgemässen Zwischenwirbelimplantates 1 dargestellt, welche ein zur Zentralachse 11 koaxiales, unteres Implantatteil 2 mit einem aussenstehenden, unteren Appositionsteil 4 und ein zur Zentralachse 11 koaxiales, oberes Implantatteil 5 mit einem aussenstehenden, oberen Appositionsteil 8 umfasst. Das untere Appositionsteil 4 weist eine untere, quer zur Zentralachse 11 stehende Appositionsfläche 19 auf, welche zur Anlage an die Deckfläche des unteren, angrenzenden Wirbelkörpers bestimmt ist. Analog weist das obere Appositionsteil 8 eine obere, quer zur Zentralachse 11 stehende Appositionsfläche 20 auf, welche zur Anlage an die Grundfläche des oberen angrenzenden Wirbelkörpers bestimmt sind. Beide Appositionsflächen 19;20 sind mit einer dreidimensionalen Strukturierung versehen und weisen je eine anteriore Seitenfläche 41;81, je eine posteriore Seitenfläche 42;82 und je zwei laterale Seitenflächen 43;44;83;84 auf (Fig. 3 und 4). 15. Ferner weist die obere

Appositionsfläche 20 des oberen Implantatteils 5 eine in sagittaler Richtung vorliegende Wölbung auf.

Das untere Implantatteil 2 umfasst eine posteriore, zur Zentralachse 11 koaxiale und zylindrische Kavität 3 mit einem anterior offenen Mantel 14 (Fig. 2). Das obere Implantatteil 5 weist einen zur Zentralachse 11 koaxialen, kreiszylindrischen Schaft 6 mit einer ein Innengewinde 7 aufweisenden, koaxialen Bohrung 30 auf (Fig. 3). Der kreiszylindrische Schaft 6 erstreckt sich in die Kavität 3 des unteren Implantatteiles 2 und ist in der Kavität 3 parallel zur Zentralachse 11 verschiebbar. Die beiden Implantatteile 2;5 sind gegen eine Rotation relativ zueinander um die Zentralachse 11 gesichert, wobei zur Sicherung gegen Rotation des oberen Implantatteils 5 gegenüber dem unteren Implantatteil 2 der kreiszylindrische Schaft 6 des oberen Implantatteils 5 zwei parallel zur Zentralachse 11 und seitlich am Schaft 6 angebrachte Keile 16 aufweist. Der Mantel 14 des unteren Implantteils 2 weist an seiner Innenseite zwei seitlich angebrachte Führungsschlitze 17 auf, welche zur Aufnahme der Keile 16 dienen. Die Keile 16 sind axial verschiebbar in den Führungsschlitzen 17 gelagert. Dabei weist der kreiszylindrische Schaft 6 am oberen Implantatteil 5 einen kleineren Durchmesser auf als die Kavität 3 am unteren Implantatteil 2, so dass die beiden Implantatteile 2;5 nur durch die beiden Keile 16 in den Führungsschlitzen 17 miteinander in Berührung stehen.

Ferner umfasst das Zwischenwirbelimplantat 1 eine Gewindespindel 9 mit einem Aussengewinde 10. Diese Gewindespindel 9 ist koaxial zur Zentralachse 11 angeordnet und weist eine untere Fläche 12 auf, welche senkrecht zur Zentralachse 11 steht und auf dem unteren Implantatteil 2 aufliegt. Das Aussengewinde 10 der Gewindespindel 9 ist zum Innengewinde 7 in der im Schaft 6 im oberen Implantatteil 5 angebrachten Bohrung 30 komplementär ausgestaltet, so dass die Gewindespindel 9 in das Innengewinde 7 einschraubbar ist. Durch Drehen der Gewindespindel 9 um die Zentralachse 11 werden die beiden Implantatteile 2;5 somit parallel zur Zentralachse 11 relativ zueinander verschoben, so dass der Abstand zwischen den beiden Appositionsteilen 4;8 stufenlos veränderbar ist. Ferner ist die Gewindespindel 9 axial fest aber um die Zentralachse 11 rotativ bewegbar mit dem unteren Implanatteil 2 verbunden. Diese Verbindung umfasst hier eine Klippverbindung, welche durch einen torusförmigen Hinterschnitt 21 an dem endständig am unteren Ende 26 der

Gewindespindel 9 angeordneten Zapfen 36 (Fig. 3) und einem in der ebenfalls zur Zentralachse 11 koaxialen Bohrung 35 angebrachten kreisringförmigen Wulst 22 realisiert ist. Durch den in den Hinterschnitt 21 am Zapfen 36 einrastbaren kreisringförmigen Wulst 22 in der Bohrung 35 werden die Gewindespindel 9 und das untere Implantatteil 2 axial fest miteinander verbunden.

Zwischen dem Aussengewinde 10 und dem endständigen Zapfen 36 umfasst die Gewindespindel 9 einen zur Zentralachse 11 koaxialen Zahnkranz 23. Ferner sind seitlich am Mantel 14 zwei senkrecht zur Zentralachse 11 verlaufende Schlitze 15 angebracht. Zur Verstellung des Abstandes zwischen den Appositionsteilen 4;8 mittels Drehen der Gewindespindel 9 um die Zentralachse 11 wird das beispielsweise gabelförmige Vorderteil eines Instrumentes in den Schlitzen 15 positioniert und das Instrument abgestützt. Das Instrument umfasst vorzugsweise am hinteren rotative Antriebsmittel, beispielsweise einen Drehgriff, welcher durch eine Achse mit einem beispielsweise am vorderen Ende des Instrumentes angeordneten Umlenkgetriebe verbunden ist. Durch das Umlenkgetriebe wird die Rotationsbewegung des Drehgriffes beispielsweise in eine Rotationsbewegung mit senkrecht zur Achse des Drehgriffes stehender Rotationsachse gewandelt, so dass bei positioniertem Instrument das endständige Zahnrad des Umlenkgetriebes mit dem Zahnkranz 23 in Eingriff bringbar ist.

Die anterioren Seitenflächen 41;82 der zwei Appositionsteile 4;8 sind mit je einer kreisförmigen Ausnahme 13;18 ausgestaltet. Diese Ausnahmen 13;18 eignen sich zur Anlagerung von Spongiosa.

Eine Bohrung 32 mit Innengewinde 25 (Fig. 5) durchdringt die Aussenwand des Schaftes 6 quer zur Zentralachse 11 derart, dass mittels einer in das Innengewinde 25 einschraubbaren Stellschraube 24 die Gewindespindel 9 im oberen Implantatteil 5 blockierbar ist. Die Stellschraube 24 dient zur Rotationssicherung der Gewindespindel 9 nach Einstellung des gewünschten Abstandes zwischen den Appositionsteilen 4;8.

Patentansprüche

1. Zwischenwirbelimplantat (1) mit

A) einem unteren Implantatteil (2), welches eine Zentralachse (11) und einen zur Anlage an die Deckfläche des angrenzenden unteren Wirbels bestimmten Appositionsteil (4) umfasst;

B) einem oberen Implantatteil (5) mit einer ein Innengewinde (7) aufweisenden Bohrung (30) und Zentralachse (11) und einem zur Anlage an die Deckfläche des angrenzenden oberen Wirbels bestimmten Appositionsteil (8); wobei

C) die beiden Implantatteile (2;5) relativ zueinander gegen Rotation um die Zentralachse (11) gesichert sind; sowie

D) einer im oberen Implantatteil (5) geführten und mit dem unteren Implantatteil (2) verbundenen Gewindespindel (9) mit Aussengewinde (10), welches mit dem Innengewinde (7) zusammenwirkt; wobei

E) die beiden Implantatteile (2;5) und die Gewindespindel (9) koaxial längs ihrer gemeinsamen Zentralachse (11) angeordnet sind,

dadurch gekennzeichnet, dass

F) die Gewindespindel (9) axial fest aber rotativ beweglich mit dem unteren Implantatteil (2) verbunden ist; und

G) durch Verdrehen der Gewindespindel (9) auf dem Innengewinde (7) der Abstand zwischen den beiden Appositionsteilen (4;8) stufenlos veränderbar ist.

2. Zwischenwirbelimplantat (1) nach Anspruch 1, dadurch gekennzeichnet, dass die Gewindespindel (9) mittels einer Klippverbindung am unteren Implantatteil (2) axial fest aber rotativ beweglich befestigt ist.

3. Zwischenwirbelimplantat (1) nach Anspruch 2, dadurch gekennzeichnet, dass die Klippverbindung elastisch deformierbare Segmente an der Gewindespindel (9) und am unteren Implantatteil (4) umfasst.

4. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Gewindespindel (9) einen zur Zentralachse (11) konzentrischen Zahnkranz (23) umfasst.

5. Zwischenwirbelimplantat (1) nach Anspruch 3 oder 4, dadurch gekennzeichnet, dass die Klippverbindung aus einem torusförmigen Hinterschnitt (21) in der Gewindespindel (9) und einem damit korrespondierenden ringförmigen Wulst (22) am unteren Implantatteil (2) gebildet wird.

6. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass die Gewindespindel (9) eine senkrecht zur Zentralachse (11) stehende untere, auf dem unteren Implantatteil (2) aufliegende Fläche (12) aufweist.

7. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass der untere Implantatteil (2) koaxial zur Zentralachse (11) eine posteriore, hohlzylindrische Kavität (3) mit einem Mantel (14) umfasst.

8. Zwischenwirbelimplantat (1) nach Anspruch 7, dadurch gekennzeichnet, dass der obere Implantatteil (8) einen im wesentlichen kreiszylindrischen Schaft (6) umfasst und die Bohrung (30) mit Innengewinde (7) den Schaft (6) axial durchdringt.

9. Zwischenwirbelimplantat (1) nach Anspruch 7, dadurch gekennzeichnet, dass der Mantel (14) des unteren Implantatteils (2) mindestens einen senkrecht zur Zentralachse (11) stehenden Schlitz (15) aufweist, welcher geeignet ist ein Instrument gegenüber dem Zahnkranz (23) zu positionieren und abzustützen.

10. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass die zwei Appositionsteile (4;8) je eine anteriore Seitenfläche (41;81) aufweisen, und dass der Mantel (14) anterior offen ist.

11. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, dass zur Sicherung gegen Rotation des oberen Implantatteils (5) gegenüber dem unteren Implantatteil (2), der kreiszylindrische Schaft (6) des oberen Implantatteils (5) mindestens einen parallel zur Zentralachse (11) und seitlich angebrachten Keil (16) aufweist und der Mantel (14) des unteren Implantteils (2) an seiner Innenseite mindestens einen seitlich angebrachten Führungsschlitz (17) zur axial verschiebbaren Aufnahme des mindestens einen Keils (16) aufweist.

12. Zwischenwirbelimplantat (1) nach Anspruch 11, dadurch gekennzeichnet, dass der kreiszylindrische Schaft (6) einen geringeren Umfang aufweist als die Kavität (3), so dass sich die beiden Bauteile nur durch die beiden Keile (16) in den Führungsschlitzen (17) berühren.

13. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 12, dadurch gekennzeichnet, dass das Innengewinde (7) und das Aussengewinde (10) der Gewindespindel (9) selbsthemmend ausgebildet sind.

14. Zwischenwirbelimplantat (1) nach Anspruch 13, dadurch gekennzeichnet, dass die Steigung des Innengewindes (7) und des Aussengewindes (10) im Bereich von 0,5 bis 1,0 mm, vorzugsweise von 0,6 – 0,8 mm liegt.

15. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 14, dadurch gekennzeichnet, dass sowohl das Innengewindes (7) als auch das Aussengewinde (10) als Rechtsgewinde ausgebildet sind.

16. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 15, dadurch gekennzeichnet, dass die beiden Appositionsteile (4;8) je eine anteriore Seitenfläche (41;81) aufweisen, welche mit je einer kreisförmigen Ausnahme (13;18) versehen sind, welche zur Anlagerung von Spongiosa geeignet sind.

17. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 16, dadurch gekennzeichnet, dass die beiden Appositionsteile (4,8) als quer zur Zentralachse (11) stehende, plattenförmige Elemente mit einer zur Anlage an die Deckfläche des angrenzenden Wirbels bestimmten Appositionsfläche (19;20) ausgebildet sind.

18. Zwischenwirbelimplantat (1) nach Anspruch 17, dadurch gekennzeichnet, dass die Appositionsflächen (19;20) nicht orthogonal zur Zentralachse (11) angeordnet sind und vorzugsweise einen Winkel 80° bis 89 ° mit der Zentralachse (11) einschliessen.

19. Zwischenwirbelimplantat (1) nach Anspruch 18, dadurch gekennzeichnet, dass die beiden Appositionsflächen (19;20) einen Winkel von 2° bis 20° untereinander einschliessen.

20. Zwischenwirbelimplantat (1) nach einem der Ansprüche 17 bis 19, dadurch gekennzeichnet, dass die beiden Appositionsteile (4;8) je zwei zur sagittalen Richtung parallele, laterale Seitenflächen (43;44;83;84) aufweisen und mindestens eine der beiden Appositionsflächen (19,20), vorzugsweise diejenige des oberen Implantatteils (5) eine in sagittaler Richtung verlaufende Wölbung aufweist.

21. Zwischenwirbelimplantat (1) nach einem der Ansprüche 8 bis 20, dadurch gekennzeichnet, dass der Schaft (6) eine quer zur Zentralachse (11) angeordnete Bohrung (32) mit einem Gewinde (25) aufweist, und eine Stellschraube (24) zur Rotationssicherung der Gewindespindel (9) um die Zentralachse (11) in das Gewinde (25) schraubbar ist.

22. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 21, dadurch gekennzeichnet, dass es mindestens teilweise aus einem röntgenstrahlendurchlässigen Material gefertigt ist, vorzugsweise aus PEEK.

GEÄNDERTE ANSPRÜCHE
[beim Internationalen Büro am 07 Oktober 2003 (07.10.03) eingegangen;
ursprüngliche Ansprüche 1-4 geändert (1 Seite)]

1. Zwischenwirbelimplantat (1) mit
A) einem unteren Implantatteil (2), welches eine Zentralachse (11) und einen zur Anlage an die Deckfläche des angrenzenden unteren Wirbels bestimmten Appositionsteil (4) umfasst;
B) einem oberen Implantatteil (5) mit einer ein Innengewinde (7) aufweisenden Bohrung (30) und Zentralachse (11) und einem zur Anlage an die Deckfläche des angrenzenden oberen Wirbels bestimmten Appositionsteil (8); wobei
C) die beiden Implantatteile (2;5) relativ zueinander gegen Rotation um die Zentralachse (11) gesichert sind; sowie
D) einer im oberen Implantatteil (5) geführten und mit dem unteren Implantatteil (2) verbundenen Gewindespindel (9) mit Aussengewinde (10), welches mit dem Innengewinde (7) zusammenwirkt; wobei
E) die beiden Implantatteile (2;5) und die Gewindespindel (9) koaxial längs ihrer gemeinsamen Zentralachse (11) angeordnet sind,
F) die Gewindespindel (9) axial fest aber rotativ beweglich mit dem unteren Implantatteil (2) verbunden ist; und
G) durch Verdrehen der Gewindespindel (9) auf dem Innengewinde (7) der Abstand zwischen den beiden Appositionsteilen (4;8) veränderbar ist,
dadurch gekennzeichnet, dass
H) der Abstand zwischen beiden Appositionsteilen (4;8) stufenlos veränderbar ist.

2. Zwischenwirbelimplantat (1) nach Anspruch 1, dadurch gekennzeichnet, dass die Gewindespindel (9) mittels einer Klippverbindung am unteren Implantatteil (2) axial fest aber rotativ beweglich befestigt ist.

3. Zwischenwirbelimplantat (1) nach Anspruch 2, dadurch gekennzeichnet, dass die Klippverbindung elastisch deformierbare Segmente an der Gewindespindel (9) und am unteren Implantatteil (4) umfasst.

4. Zwischenwirbelimplantat (1) nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, dass die Gewindespindel (9) einen zur Zentralachse (11) konzentrischen Zahnkranz (23) umfasst.

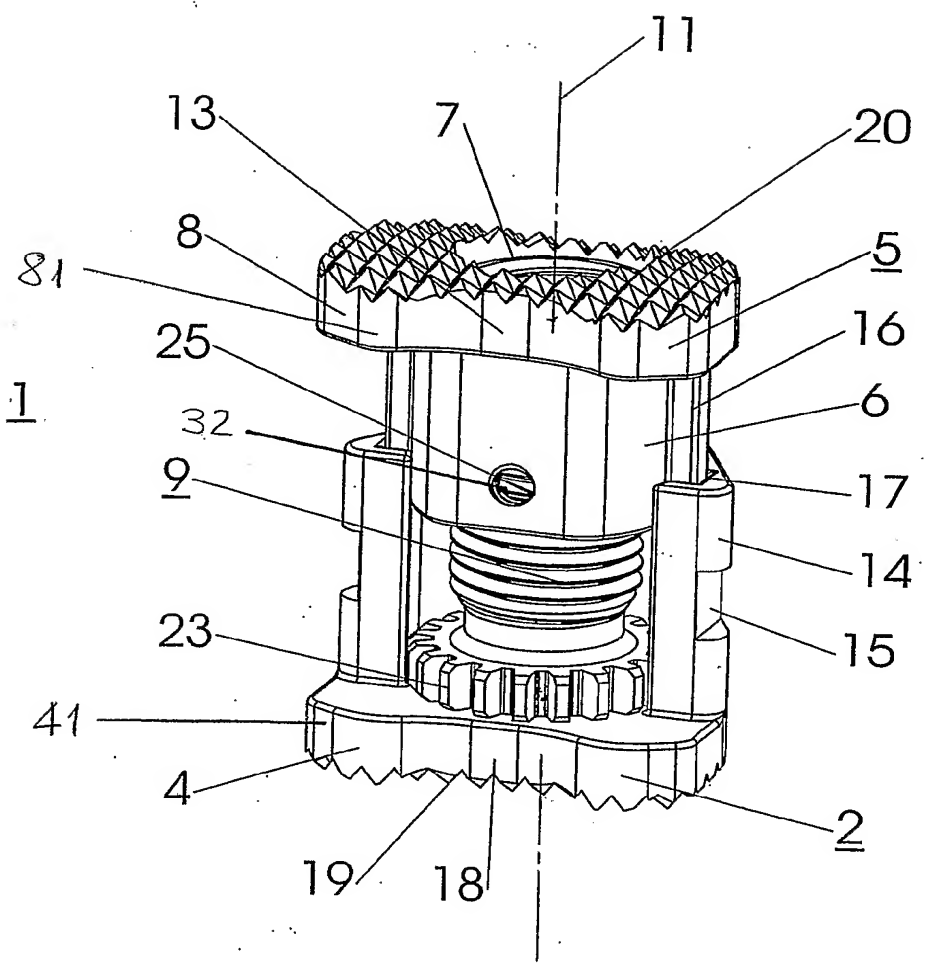


Fig. 1:

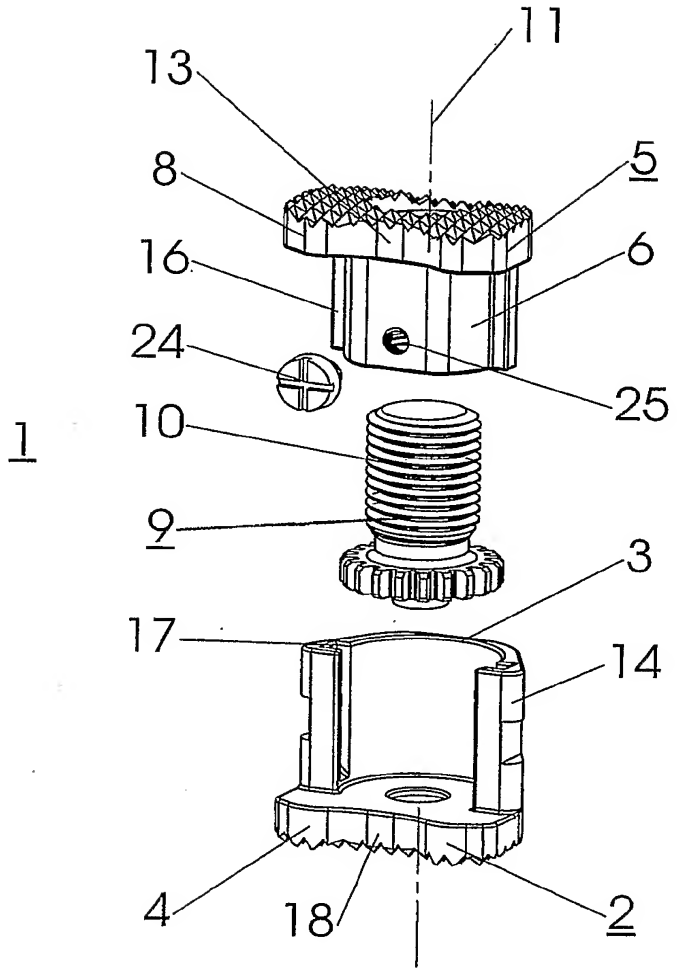


Fig. 2:

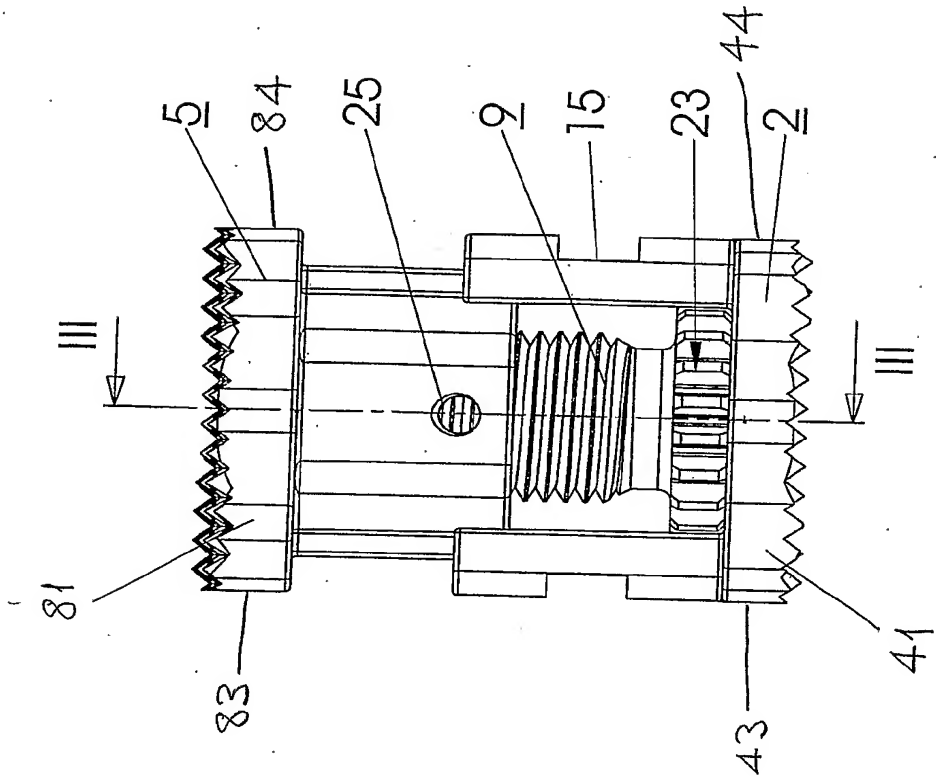

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Fig. 4:

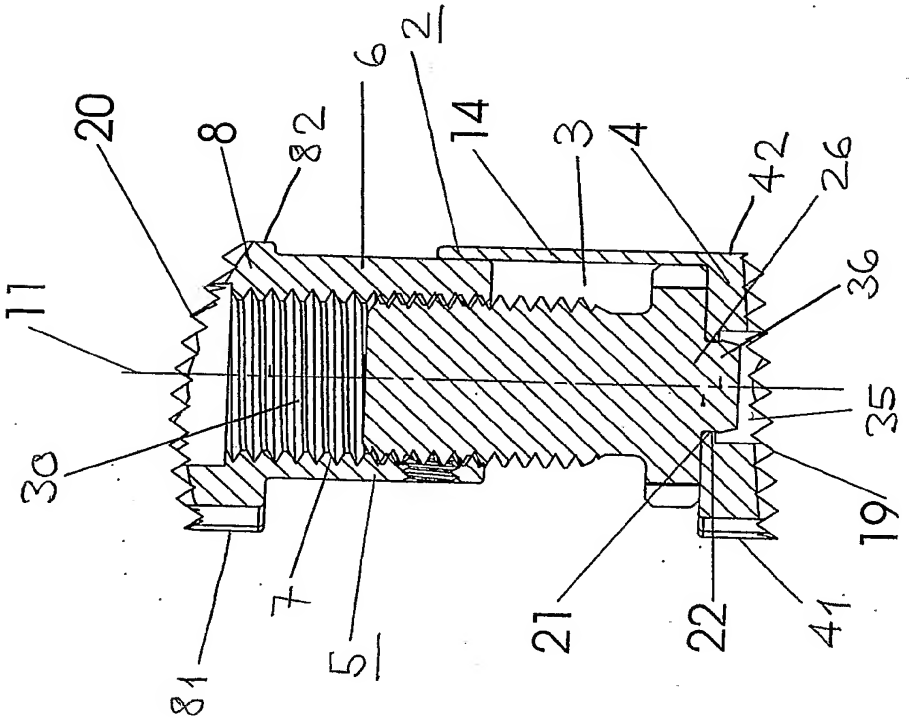
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Fig. 3:

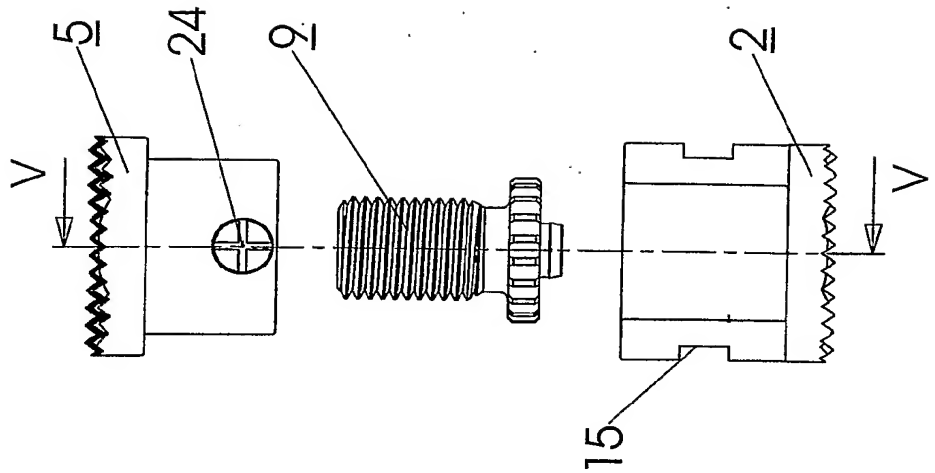

Fig. 6:

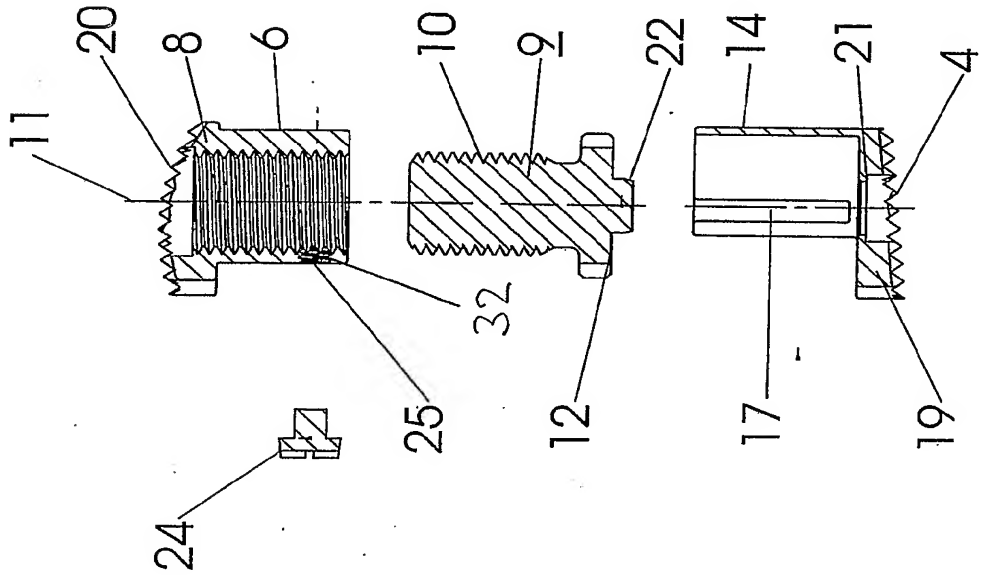

Fig. 5:

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH 02/00674

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 91 01 603 U (ESKA MEDICAL LÜBECK MEDIZINTECHNIK GMBH & CO) 2 May 1991 (1991-05-02) figures 1,2 page 9	1,17
A	US 6 190 414 B1 (YOUNG WAYNE P ET AL) 20 February 2001 (2001-02-20) figures 6-8,16-18	4
A	US 6 193 756 B1 (DONNO COSIMO ET AL) 27 February 2001 (2001-02-27) figure 8	17-19
A	US 2002/161441 A1 (BENOIT ALFRED ET AL) 31 October 2002 (2002-10-31) figures 1,3	20

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search	Date of mailing of the international search report
27 August 2003	03/09/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Josten, S

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/CH 02/00674

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 702 455 A (SAGGAR RAHUL) 30 December 1997 (1997-12-30) figure 1	21
A	US 2002/082695 A1 (NEUMANN CARSTEN) 27 June 2002 (2002-06-27) cited in the application figures 2-4,8,12	1-22

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

nation on patent family members

International Application No
PCT/CH 02/00674

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		DE 20121560 U1	02-01-2003
		EP 1219266 A1	03-07-2002
		JP 2002238929 A	27-08-2002

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/CH 02/00674

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A61F2/44

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

EPO-Internal

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	DE 91 01 603 U (ESKA MEDICAL LÜBECK MEDIZINTECHNIK GMBH & CO) 2. Mai 1991 (1991-05-02) Abbildungen 1,2 Seite 9	1,17
A	US 6 190 414 B1 (YOUNG WAYNE P ET AL) 20. Februar 2001 (2001-02-20) Abbildungen 6-8,16-18	4
A	US 6 193 756 B1 (DONNO COSIMO ET AL) 27. Februar 2001 (2001-02-27) Abbildung 8	17-19
A	US 2002/161441 A1 (BENOIT ALFRED ET AL) 31. Oktober 2002 (2002-10-31) Abbildungen 1,3	20

-/--

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

[X] Siehe Anhang Patentfamilie

° Besondere Kategorien von angegebenen Veröffentlichungen :
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Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
27. August 2003	03/09/2003

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Josten, S

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INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
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C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	US 5 702 455 A (SAGGAR RAHUL) 30. Dezember 1997 (1997-12-30) Abbildung 1	21
A	US 2002/082695 A1 (NEUMANN CARSTEN) 27. Juni 2002 (2002-06-27) in der Anmeldung erwähnt Abbildungen 2-4,8,12	1-22

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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen zur selben Patentfamilie gehören

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Im Recherchenbericht angeführtes Patentdokument		Datum der Veröffentlichung	Mitglied(er) der Patentfamilie		Datum der Veröffentlichung
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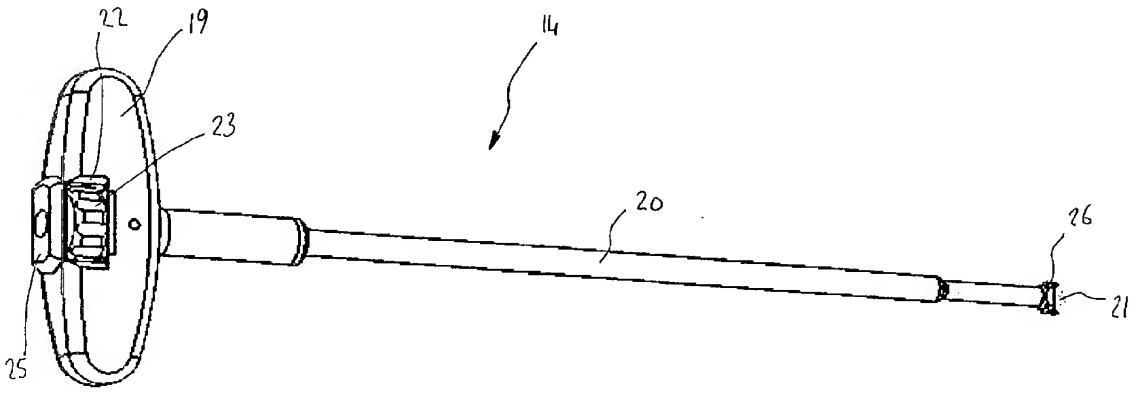
[Suite sur la page suivante]

(54) Title: DEVICE FOR THE PLACEMENT OF A REVERSIBLE INTERSOMATIC CAGE BETWEEN THE VERTEBRAL BODIES OF A SPINAL COLUMN

(54) Titre : DISPOSITIF DE MISE EN PLACE D'UNE CAGE INTERSOMATIQUE REVERSIBLE ENTRE LES CORPS VERTEBRAUX



(57) Abstract: The invention relates to a placement device, comprising a tool (14) with a manipulating grip (19) fixed to a tube (20), assembly means (23, 24, 33) and a follower bar (21) guided and immobilised within the tube (20).

(57) Abrégé : Le dispositif de mise en place suivant la présente invention comporte un outil (14) qui est constitué d'une poignée de préhension (19) solidaire d'un tube (20), de moyens d'assemblage (23, 24, 33) et d'une tige suiveuse (21) guidée et immobilisée à l'intérieur du tube (20).

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— *avant l'expiration du délai prévu pour la modification des revendications, sera republiée si des modifications sont reçues*

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

DISPOSITIF DE MISE EN PLACE D'UNE CAGE INTERSOMATIQUE REVERSIBLE ENTRE LES CORPS VERTEBRAUX

La présente invention est relative à un dispositif de mise en place d'une cage intersomatique entre les corps vertébraux d'une colonne vertébrale.

Egalement, la présente invention est relative à une tige suiveuse permettant le repérage de la cage intersomatique pendant l'opération chirurgicale.

Le dispositif de mise en place d'une cage intersomatique suivant la présente invention comporte un outil qui est constitué d'une poignée de préhension solidaire d'un tube et des moyens d'assemblage pour la fixation d'une tige suiveuse à l'intérieur du tube.

Le dispositif de mise en place suivant la présente invention comporte des moyens d'assemblage qui sont constitués d'une tige guidée à l'intérieur de l'alésage du tube, d'une molette permettant l'entraînement en rotation de la tige, et d'un profil hexagonal prévu dans l'alésage dudit tube pour le blocage en rotation de la tige suiveuse à l'intérieur du tube.

Le dispositif de mise en place suivant la présente invention comporte une poignée comprenant un logement à l'intérieur duquel tourne en rotation la molette afin d'entraîner à l'intérieur de l'alésage du tube la tige, ledit logement étant fermé au dessus de la molette par une platine formant une zone de frappe sur l'outil.

Le dispositif de mise en place suivant la présente invention comporte une tige suiveuse comprenant une partie filetée et à l'opposé de cette dernière un profil hexagonal ou analogue se prolongeant par une extrémité filetée.

Le dispositif de mise en place suivant la présente invention comporte un tube comprenant à l'opposé de la poignée des ergots.

Le dispositif de mise en place suivant la présente invention comporte un tube comprenant dans sa partie interne un premier alésage qui se prolonge par un second alésage dont le diamètre interne est inférieur à celui du premier.

La description qui va suivre en regard des dessins annexés, donnés à titre d'exemples non limitatifs, permettra de mieux comprendre l'invention, les caractéristiques qu'elle présente et les avantages qu'elle est susceptible de procurer :

Figure 1 est une vue en perspective illustrant la cage intersomatique suivant la présente invention.

Figure 2 est une vue représentant les corps vertébraux des vertèbres sus et sous jacentes d'une colonne vertébrale vue de face entre lesquels sont introduit les cages intersomatiques suivant la présente invention.

Figure 3 est une vue représentant les corps vertébraux des vertèbres sus et sous jacentes d'une colonne vertébrale vue de profil entre lesquels sont introduites les cages intersomatiques suivant la présente invention.

Figure 4 est une vue en perspective montrant le dispositif ou l'instrumentation pour la mise en place de la cage intersomatique.

Figure 5 est une vue en perspective représentant une tige suiveuse permettant la liaison mécanique entre la cage intersomatique et le dispositif de mise en place suivant la présente invention.

Figure 6 est une vue en coupe illustrant la tête de manœuvre du dispositif de mise en place suivant la présente invention.

Figure 7 est une vue en coupe montrant la fixation de la tige suiveuse à l'extrémité du dispositif de mise en place suivant la présente invention.

Figures 8 et 9 sont des vues représentant la cage intersomatique montée sur le dispositif de mise en place suivant la présente invention.

On a montré en figure 1 une cage intersomatique 1 présentant un profil courbé pour affecter par exemple la forme d'une demi banane.

La cage intersomatique 1 est constituée d'un corps 2 réalisé dans un matériau radio translucide, c'est à dire, qu'elle n'est pas visible lors de prises de vue radiologique. Le matériau utilisé peut être, par exemple, du fait de ses caractéristiques techniques et physiques un matériau commercialisé sous le nom de PEEK.

La cage intersomatique 1 est constituée d'un corps 2 présentant en son milieu un espace traversant 3 destiné à recevoir, par exemple, un greffon osseux non représenté.

Le corps 2 comporte des bords supérieurs 4 et inférieurs 5, des face latérales courbes 6, 7 réunies entre elles par une face avant 8 à profil arrondi et une face arrière 9 plane, l'ensemble délimitant l'espace interne 3.

Les bords supérieurs 4 et inférieurs 5 comportent respectivement de part et d'autre de l'espace interne 3 des dents 10 à profil incliné qui sont dirigées vers la face arrière 9 du corps 2 de la cage 1.

Le profil des dents 10 est prévu pour constituer un élément de retenue de la cage intersomatique 1 entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale.

La face latérale 6 formant la face interne au rayon de courbure du corps 2 en forme de demi banane est percée de deux trous 11 et 12 débouchant à l'intérieur de l'espace interne 3. De fait, l'autre face latérale 7 constitue la face externe au rayon de courbure du corps 2 en forme de demi banane.

La face arrière 9 est percée d'un alésage fileté 13 qui est destiné à coopérer avec un outil 14 pour l'introduction et la manipulation de la cage intersomatique 1 entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale.

L'alésage fileté 13 est prévu pour déboucher à l'intérieur de l'espace interne 3 du corps 2 de la cage intersomatique 1.

Le corps 2 comporte, au niveau de la jonction entre les faces latérales 6, 7 avec la face arrière 9 et de part et d'autre de l'alésage 13, deux encoches 15 et 16 débouchant ou non à l'intérieur de l'espace interne 3 du corps 2 de la cage intersomatique 1.

Le corps 2 de la cage intersomatique 1 comporte au niveau de la face avant 8 un premier marqueur 17 disposé suivant une direction verticale et au niveau de la face arrière 9 un second marqueur 18 placé suivant une direction horizontale et perpendiculaire au premier.

Le premier marqueur 17 est positionné à l'avant de la cage intersomatique 1 et centré sur l'axe principal de cette dernière de manière que la distance entre les faces internes et externes soit identique.

Le second marqueur 18 est positionné suivant une direction horizontale qui est décalée par rapport aux axes principaux de la face arrière 9 ou de l'alésage fileté 13 de la cage intersomatique 1.

Le décalage du second marqueur 18 sur la face arrière 9 permet le repérage radiographique entre la cage intersomatique droite et gauche lors d'une vue de face de la colonne vertébrale d'un patient (figure 2).

En effet la cage intersomatique 1 suivant la présente invention est réversible, c'est à dire, quelle est susceptible d'être implantée entre les corps vertébraux à droite et à gauche de l'axe vertical passant par les vertèbres de la colonne vertébrale.

Egalement lors d'une vue de profil la position des marqueurs 17 et 18 entre les deux cages intersomatiques 1 implantés entre les corps vertébraux VS, VI permet de vérifier l'enfoncement respectif des deux cages entre elles (figure 3).

On note que sur la vue de profil la cage intersomatique 1 de droite est celle présentant le marqueur 18 en position haute, tandis que la cage intersomatique 1 de gauche est repérée par le marqueur 18 se trouvant en position la plus basse.

Cette mise en place à droite et gauche de la cage intersomatique 1 est obtenue par une simple rotation de cette dernière autour de son axe longitudinal afin que

chaque face interne 6 de plus petit rayon de courbure soit toujours disposée l'une en face de l'autre.

Les marqueurs 17, 18 sont réalisés dans un fil cylindrique ou d'une autre forme géométrique traversant de part en part la cage intersomatique 1.

Les marqueurs 17, 18 sont réalisés dans un matériau susceptible d'être visible lors d'un cliché radiographique de manière à permettre de visualiser la position des cages intersomatiques 1 entre elles et par rapport aux corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale.

En effet, il est généralement introduit entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale deux cages intersomatiques 1 qui sont positionnées l'une par rapport à l'autre de manière que les faces latérales internes 6 soient disposées l'une en face de l'autre.

Ainsi, les marqueurs 17 et 18 permettent de vérifier la position des deux cages l'une par rapport à l'autre et de repérer la cage droite de la cage gauche lorsqu'elles sont introduites entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale (figures 2, 3).

On constate que lors d'une vue de face de la colonne vertébrale il est placée entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI une cage 1 à droite et une cage à gauche de l'axe vertical de ladite colonne vertébrale.

Ainsi, la cage intersomatique 1 dite à droite est repérée grâce à la position des marqueurs 17, 18 dont le second 18 se trouve au dessus de l'alésage fileté 13 ménagé dans la face arrière 9 (figure 2).

La cage intersomatique 1 dite à gauche est repérée grâce à la position des marqueurs 17, 18 dont le second 18 se trouve au dessous de l'alésage fileté 13 ménagé dans la face arrière 9 (figure 2).

Ainsi, on constate que la cage intersomatique 1 est réversible pour être positionnée soit à droite soit à gauche et entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale

On a représenté en figures 4 à 7 un outil 14 permettant la mise en place et l'introduction de la cage intersomatique 1 entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale au moyen d'une tige suiveuse 21.

L'outil 14 est constitué d'une poignée de préhension 19 solidaire d'un tube 20 comportant dans sa partie interne un premier alésage 31 qui se prolonge par un second alésage 32 dont le diamètre interne est inférieur à celui du premier.

La poignée 19 comporte un logement 22 à l'intérieur duquel tourne en rotation une molette 23 afin d'entraîner à l'intérieur de l'alésage 31 du tube 20 une tige 24.

Le logement 22 est fermé au dessus de la molette 23 par une platine 25 formant une zone de frappe sur l'outil 14.

Le tube 20 comporte à l'opposé de la poignée 19 des ergots 26, tandis que son alésage interne 32 présente une partie 33 à profil hexagonal ou analogue.

La tige 24 est fixée à la molette 23 par l'intermédiaire d'une vis de serrage 34, tandis qu'elle comporte à l'opposé de la molette 23 un alésage fileté 27.

La tige suiveuse 21 comporte une partie filetée 28 et à l'opposé de cette dernière un profil hexagonale ou analogue 29 se prolongeant par une extrémité filetée 30.

On a montré en figures 6 à 7 l'outil 14 qui porte à l'extrémité opposée à celle de la poignée 19 une cage intersomatique 1.

La tige suiveuse 21 est assemblée de manière que son extrémité filetée 30 coopère avec l'alésage fileté 13 prévu dans la face arrière 9 du corps 2.

La tige suiveuse 21 est entraînée en rotation au moyen du profil hexagonal 29 afin que la cage intersomatique 1 soit parfaitement maintenue au bout de cette dernière.

Ensuite la tige suiveuse 21 est assemblée à l'outil 14 de manière que sa partie filetée 28 coopère avec l'alésage fileté 27 de la tige 24. La fixation de la tige suiveuse 21 est obtenue par l'entraînement en rotation de la tige 24 par la molette 23 située au niveau de la poignée 19 de l'outil 14.

La rotation de la tige 24 permet d'introduire la tige suiveuse 21 à l'intérieur de l'alésage interne 32 du tube 20 jusqu'à ce que le profil hexagonal 29 coopère avec la partie à profil complémentaire 33 dudit tube.

Le déplacement en translation de la tige suiveuse 21 à l'intérieur du tube 20 est effectué jusqu'à ce que les ergots 26 pénètrent à l'intérieur des encoches 15 et 16 prévues au niveau de la face arrière 9 de la cage intersomatique 1 (figures 8, 9).

La coopération des ergots 26 du tube 20 avec les encoches 15, 16 de la cage intersomatique 1 permet le blocage en rotation de la tige suiveuse 21 à l'intérieur dudit tube.

Ainsi, le chirurgien peut introduire entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale la première cage intersomatique 1 à l'aide de l'outil 14.

Cette introduction peut être par exemple formée par des frappes successives réalisées à l'aide d'un marteau sur la platine 25 sans risque de blocage des parties filetées de l'outil 14 avec la tige suiveuse 21 et cette dernière avec la cage intersomatique 1.

Dès que la première cage intersomatique 1 est introduite, le chirurgien retire l'outil 14 en entraînant en rotation la molette 23 pour libérer la tige suiveuse 21 bloquée en rotation par les profils complémentaires 29, 33de la tige 24 guidée à l'intérieur du tube 20.

Après le retrait de l'outil 14, on constate que la tige suiveuse 21 reste assemblée avec la première cage intersomatique 1. Ainsi, le chirurgien peut repérer visuellement la position de la cage intersomatique 1 entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale grâce à la tige suiveuse qui sort du champ opératoire.

Egalement, le chirurgien peut agir sur la tige suiveuse 21 pour changer la position de la cage intersomatique 1 entre les corps vertébraux des vertèbres sus et sous jacentes VS, VI d'une colonne vertébrale grâce à la tige suiveuse qui sort du champ opératoire.

La tige suiveuse 21 est retirée de la cage intersomatique 1 au moyen de son profil hexagonal 29 qui permet son entraînement en rotation par un outil quelconque.

Il doit d'ailleurs être entendu que la description qui précède n'a été donnée qu'à titre d'exemple et qu'elle ne limite nullement le domaine de l'invention dont on ne sortirait pas en remplaçant les détails d'exécutions décrits par tout autre équivalent.

REVENDICATIONS

1. Dispositif de mise en place d'une cage intersomatique, **caractérisé en ce** qu'il comporte un outil (14) qui est constitué d'une poignée de préhension (19) solidaire d'un tube (20), d'une tige suiveuse (21) guidée et immobilisée à l'intérieur du tube (20) et des moyens d'assemblages qui sont constitués d'une tige (24) guidée à l'intérieur d'un premier alésage (31) du tube (20), d'une molette (23) permettant l'entraînement en rotation de la tige (24), et d'un profil hexagonal (33) prévu dans un second alésage (32) dudit tube pour le blocage en rotation de la tige suiveuse (21) à l'intérieur du tube (20).

2. Dispositif de mise en place suivant la revendication 1, **caractérisé en ce que** la poignée (19) comporte un logement (22) à l'intérieur duquel tourne en rotation la molette (23) afin d'entraîner à l'intérieur de l'alésage (31) du tube (20) la tige (24), le logement (22) est fermé au dessus de la molette (23) par une platine (25) formant une zone de frappe sur l'outil (14).

3. Dispositif de mise en place suivant la revendication 1, **caractérisé en ce que** la tige suiveuse (21) comporte une partie filetée (28) et à l'opposé de cette dernière un profil hexagonal ou analogue (29) se prolongeant par une extrémité filetée (30).

4. Dispositif de mise en place suivant la revendication 1, **caractérisé en ce que** le tube (20) comporte à l'opposé de la poignée (19) des ergots (26).

5. Dispositif de mise en place suivant la revendication 1, **caractérisé en ce que** le tube (20) comporte dans sa partie interne un premier alésage (31) qui se prolonge par un second alésage (32) dont le diamètre interne est inférieur à celui du premier.

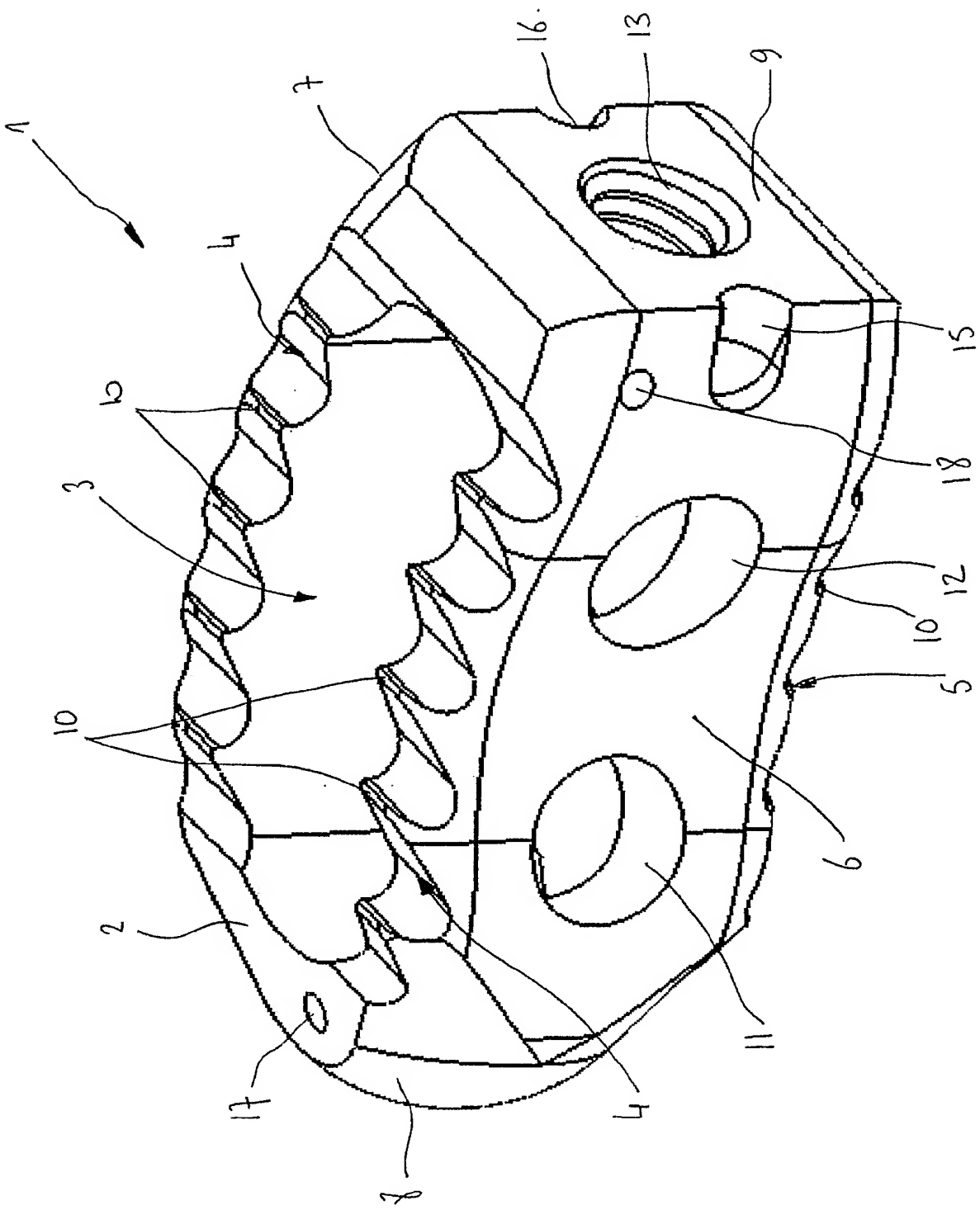

FIGURE 1

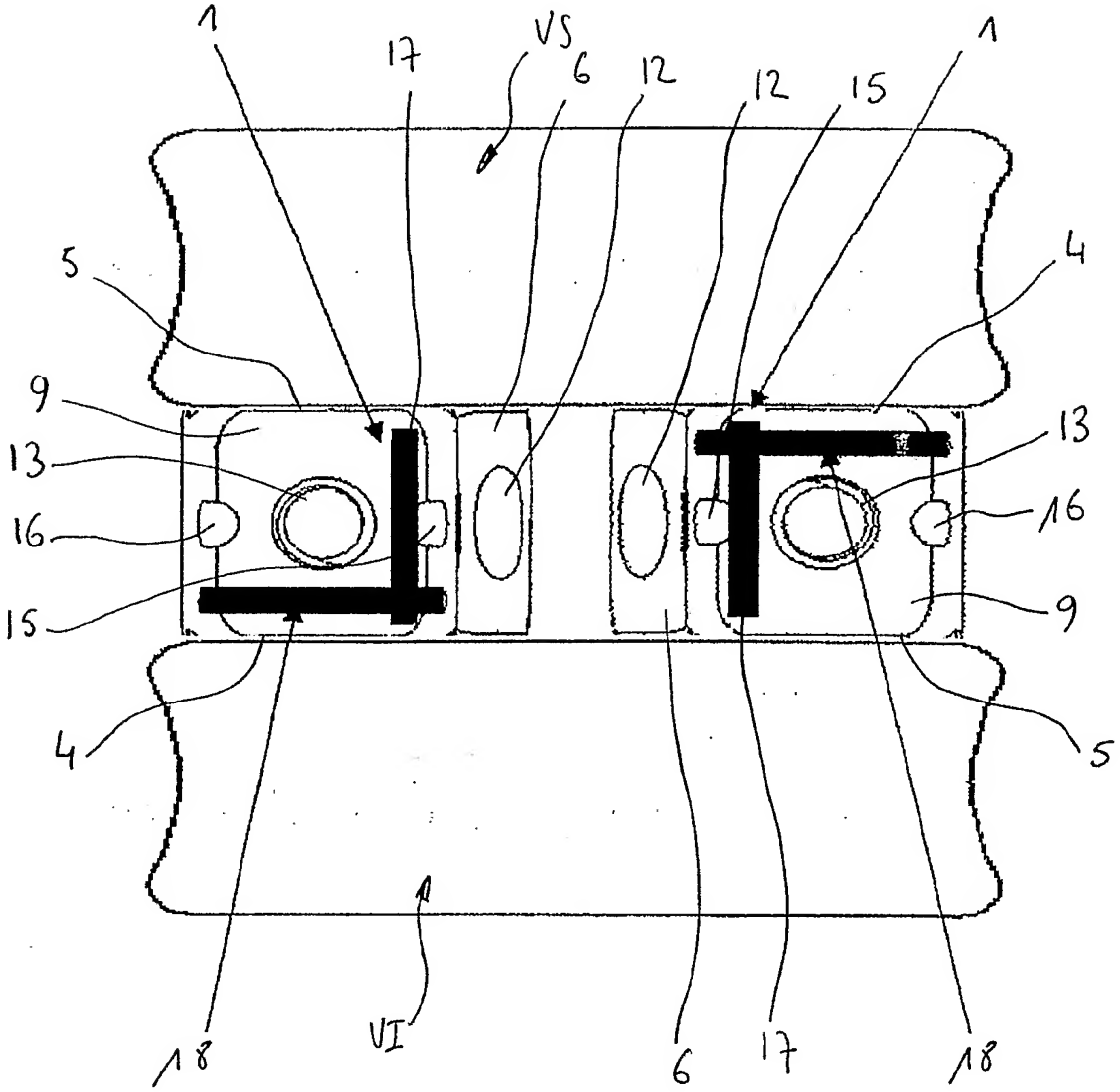

FIGURE 2

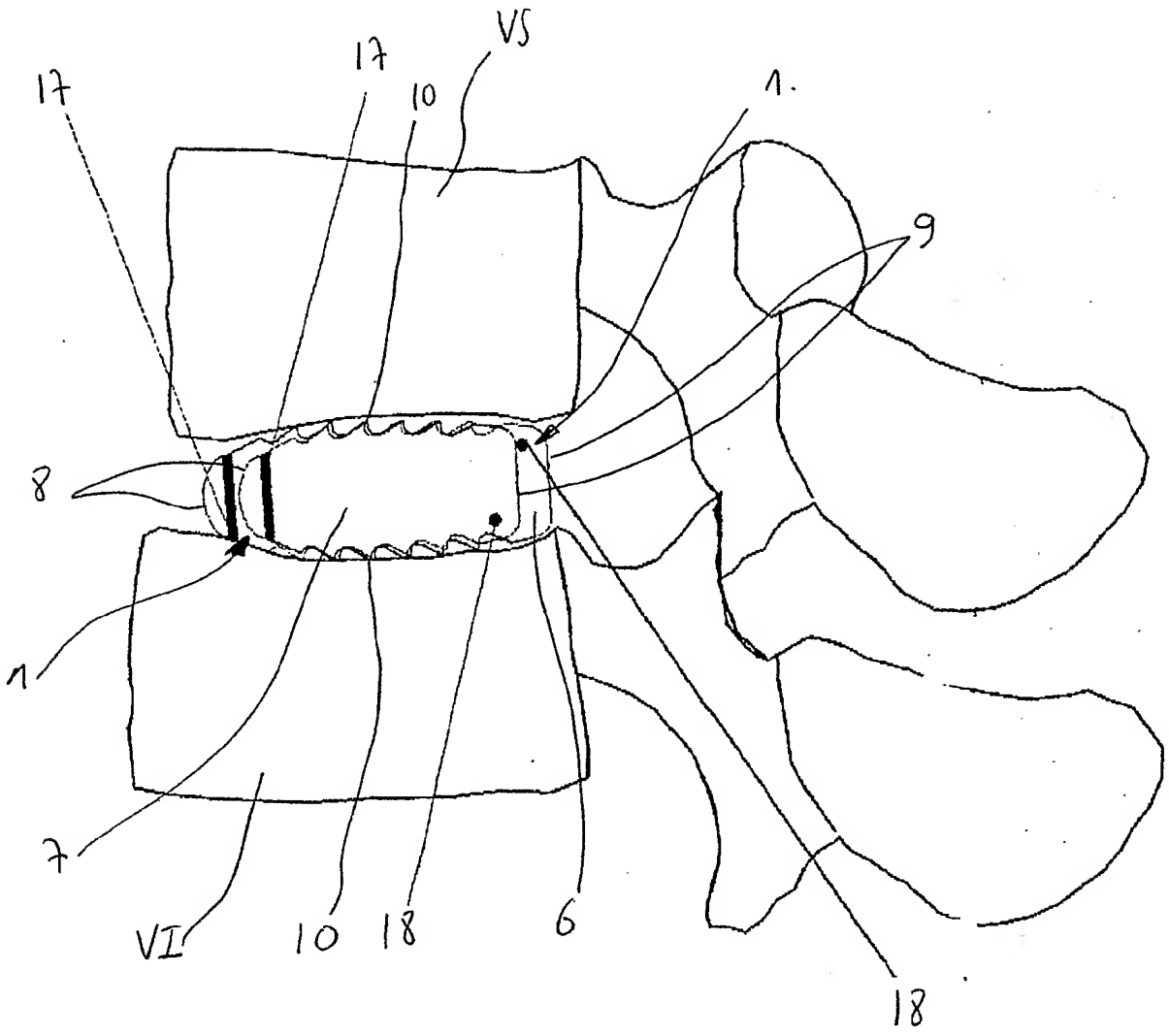

FIGURE 3

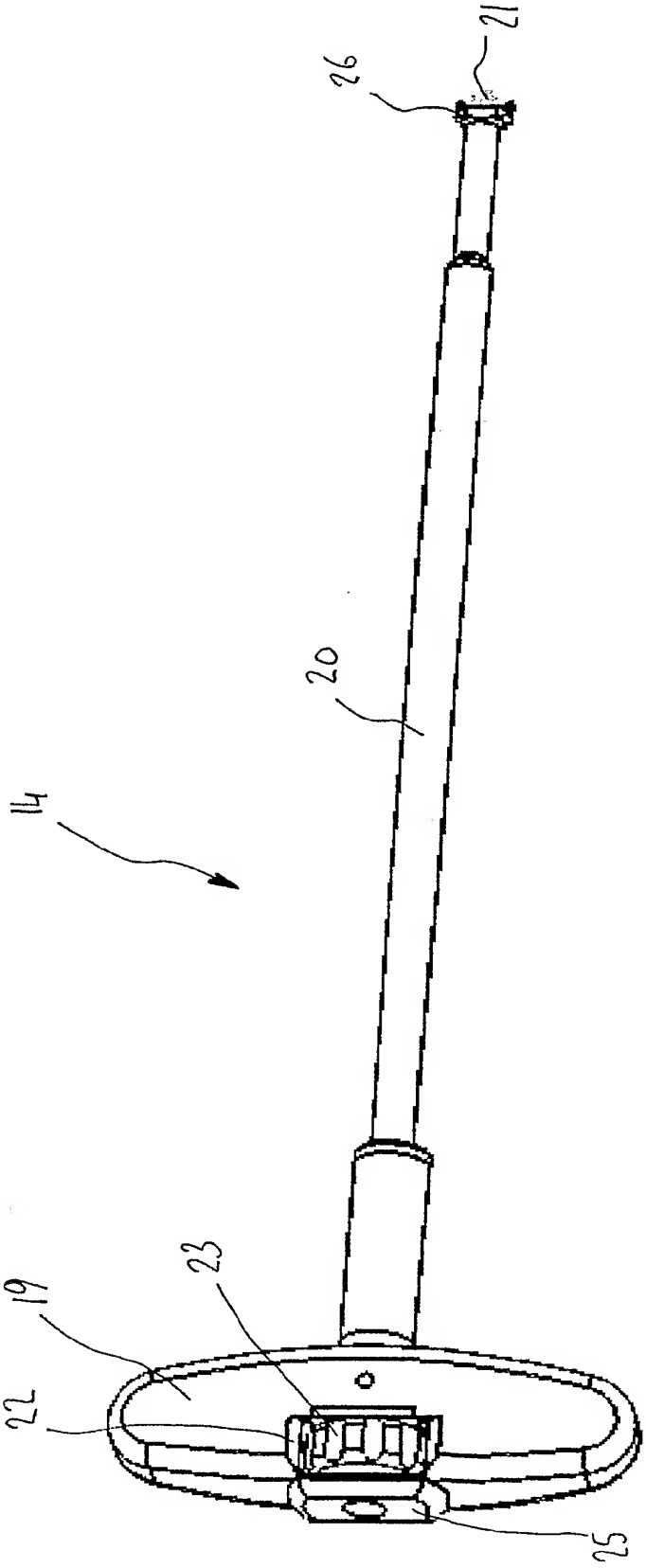

FIGURE 4

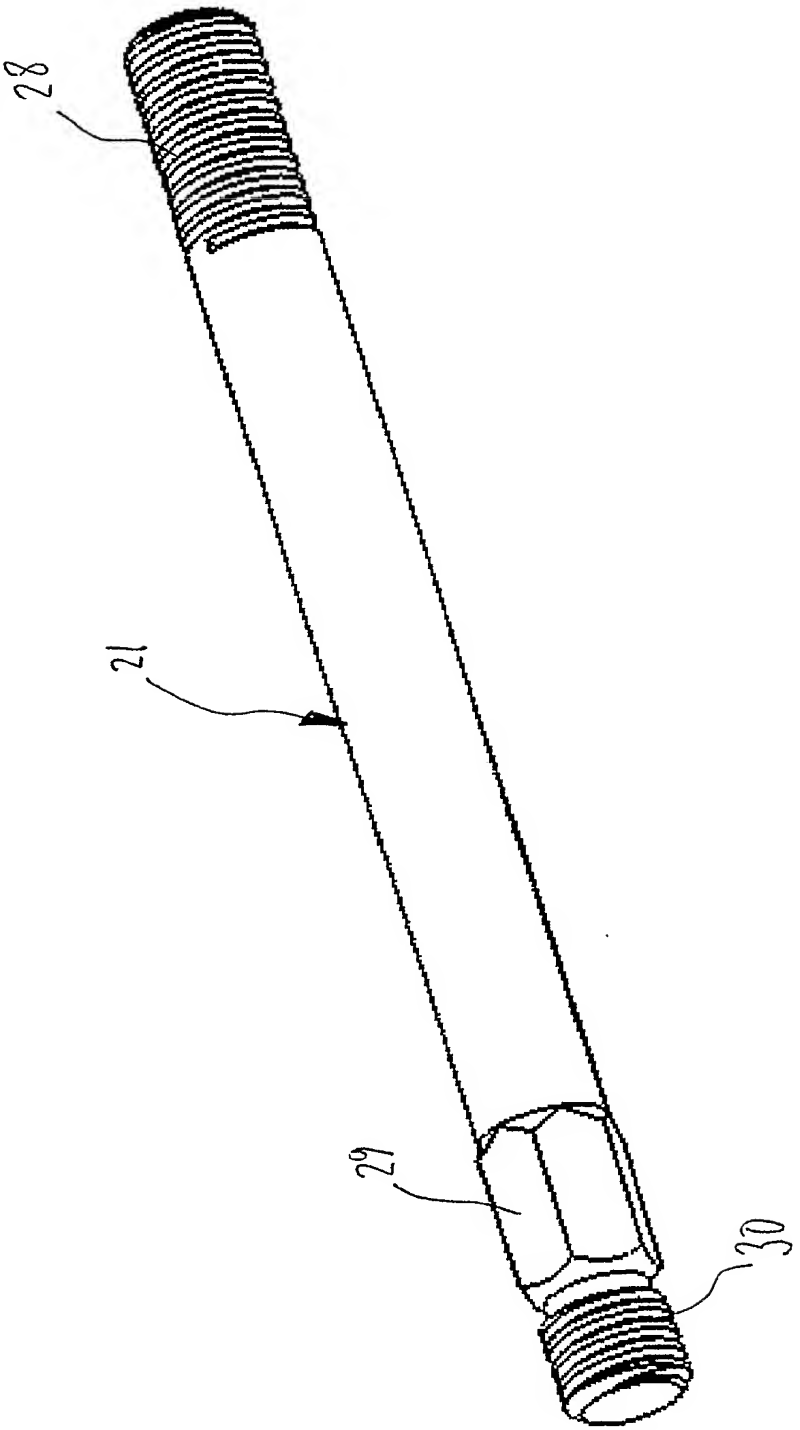

FIGURE 5

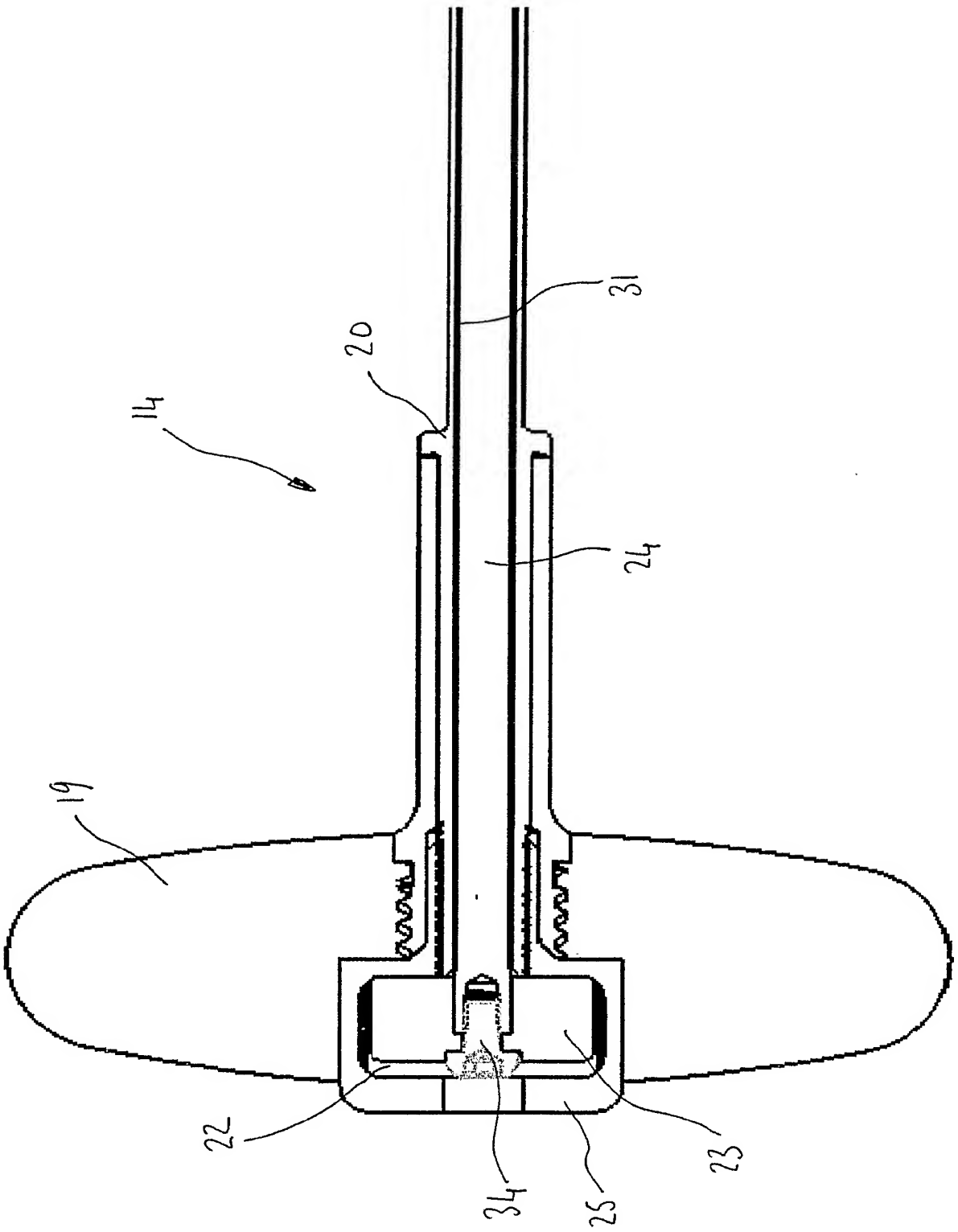

FIGURE 6

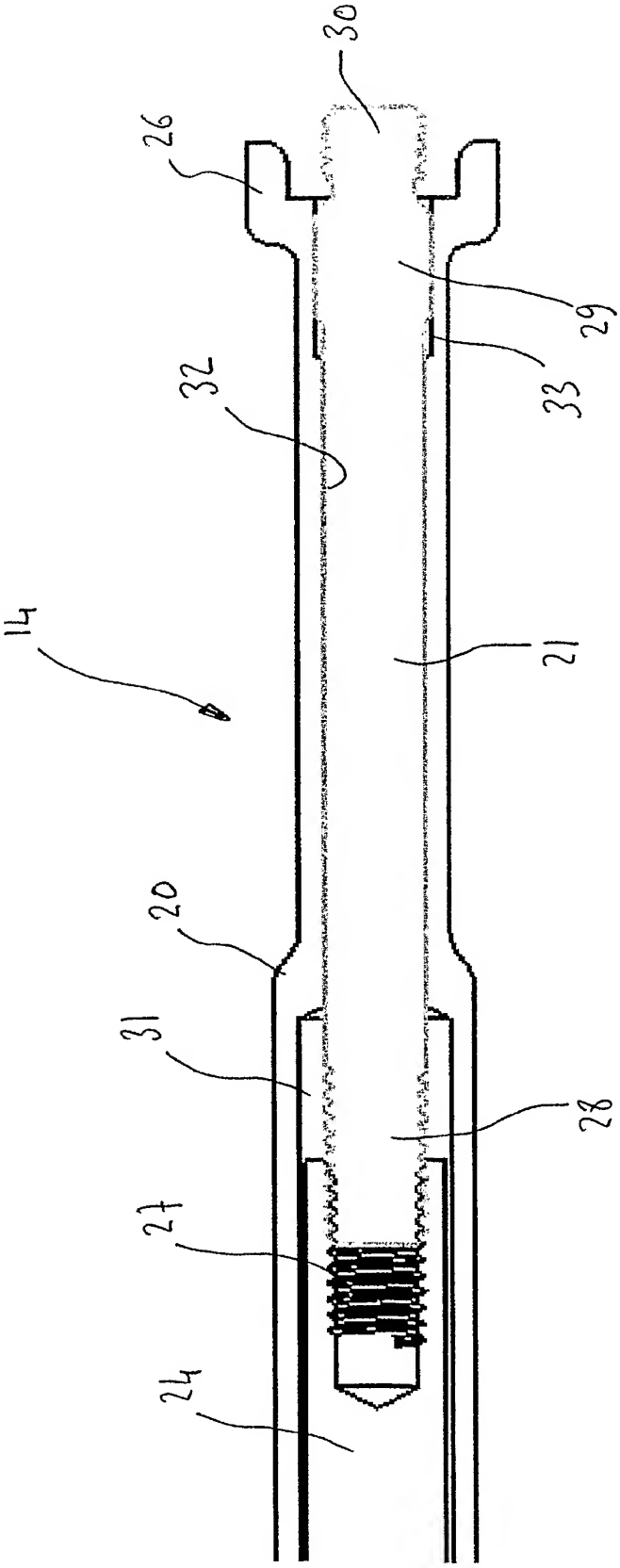

FIGURE 7

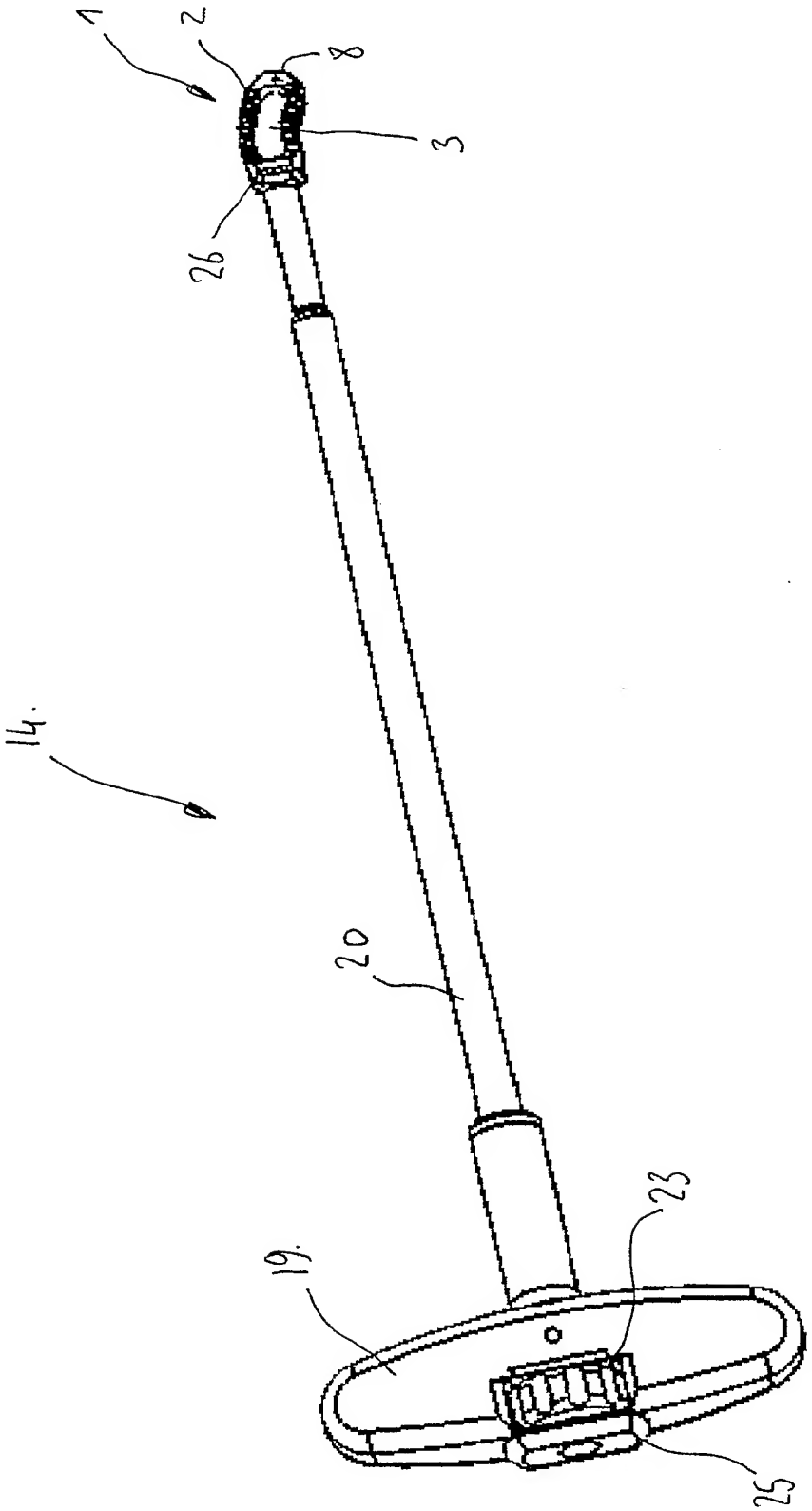

FIGURE 8

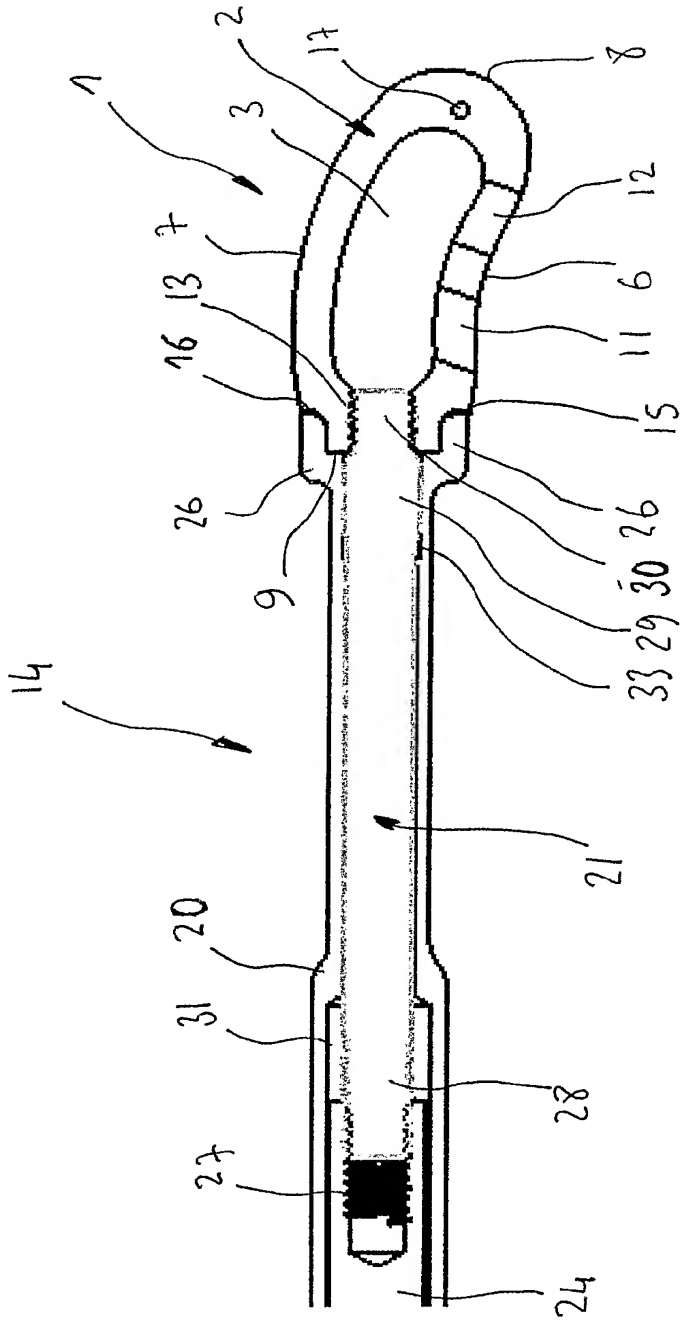

FIGURE 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/FR 03/01948

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/46 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 371 988 B1 (VAN HOECK JAMES E ET AL) 16 April 2002 (2002-04-16) column 8, line 16 - line 31 column 8, line 64 -column 9, line 14 figures 9,18	1
X	WO 01 62191 A (DERIDDER STEVEN D ;SDGI HOLDINGS INC (US); BUSKIRK DAYNA (US); LAN) 30 August 2001 (2001-08-30) page 10, line 17 -page 11, line 22 figures 7-9	1
X	US 5 885 299 A (MITCHELL STEVEN T ET AL) 23 March 1999 (1999-03-23) column 2, line 33 - line 49 column 4, line 9 -column 5, line 2 figures 1,2	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 October 2003	17/11/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Buchmann, G

INTERNATIONAL SEARCH REPORT

International Application No
PCT/FR 03/01948

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6371988 B1	16-04-2002	US 2003195629 A1	16-10-2003
		AU 732421 B2	26-04-2001
		AU 4994697 A	15-05-1998
		EP 0955961 A2	17-11-1999
		JP 2000507484 T	20-06-2000
		KR 2000052740 A	25-08-2000
		WO 9817209 A2	30-04-1998
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WO 0162191 A	30-08-2001	AU 3982201 A	03-09-2001
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US 5885299 A	23-03-1999	AU 2206997 A	01-10-1997
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		DE 69526094 D1	02-05-2002
		DE 69526094 T2	21-11-2002
		ES 2171193 T3	01-09-2002
		JP 10508766 T	02-09-1998

RAPPORT DE RECHERCHE INTERNATIONALE

Demande Internationale No
PCT/FR 03/01948

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 7 A61F2/46 A61F2/44

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 7 A61F

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)
EPO-Internal

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie °	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
X	US 6 371 988 B1 (VAN HOECK JAMES E ET AL) 16 avril 2002 (2002-04-16) colonne 8, ligne 16 - ligne 31 colonne 8, ligne 64 -colonne 9, ligne 14 figures 9,18	1
X	WO 01 62191 A (DERIDDER STEVEN D ;SDGI HOLDINGS INC (US); BUSKIRK DAYNA (US); LAN) 30 août 2001 (2001-08-30) page 10, ligne 17 -page 11, ligne 22 figures 7-9	1
X	US 5 885 299 A (MITCHELL STEVEN T ET AL) 23 mars 1999 (1999-03-23) colonne 2, ligne 33 - ligne 49 colonne 4, ligne 9 -colonne 5, ligne 2 figures 1,2	1

☐ Voir la suite du cadre C pour la fin de la liste des documents

☒ Les documents de familles de brevets sont indiqués en annexe

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"O" document se référant à une divulgation orale, à un usage, à une exposition ou tous autres moyens
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Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
30 octobre 2003	17/11/2003

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Buchmann, G

RAPPORT DE RECHERCHE INTERNATIONALE

Demande Internationale No
PCT/FR 03/01948

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
US 6371988 B1	16-04-2002	US 2003195629 A1	16-10-2003
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		WO 9733525 A1	18-09-1997
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		DE 69526632 T2	31-10-2002
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		AU 696997 B2	24-09-1998
		DE 69526094 D1	02-05-2002
		DE 69526094 T2	21-11-2002
		ES 2171193 T3	01-09-2002
		JP 10508766 T	02-09-1998

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(19) World Intellectual Property Organization
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29 January 2004 (29.01.2004)

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(10) International Publication Number
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(51) International Patent Classification[7]: A61F 2/44, 2/30

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(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 09/737,074 (CIP)
Filed on 12 December 2000 (12.12.2000)

(71) Applicant and
(72) Inventor: MALONE, David, G. [US/US]; 2722 E. 72nd Street, Tulsa, OK 74136 (US).

(74) Agent: WEEKS, R., Alan; Fellers, Snider, Blankenship, Bailey & Tippens, P.C., Suite 800, 321 South Boston Avenue, Tulsa, OK 74103-3318 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT (utility model), AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ (utility model), CZ, DE (utility model), DE, DK (utility model), DK, DM, DZ, EC, EE (utility model), EE, ES, FI (utility model), FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK (utility model), SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTERBODY SPINE FUSION CAGE

(57) Abstract: An improved spine fusion cage is provided which is particularly useful with biological compounds which are utilized in place of or in combination with a patient's bone matter. In one embodiment there is provided a cage with preselected perforated and non-perforated zones to direct the growth of bone in desired directions. In another embodiment there is provided a cage having inner and outer perforated cage bodies separated by an annulus. An end closure with occluding surfaces suitable for introduction into the annulus serves to establish one or more desired zones or patterns of occluded apertures in the cage body. In still another embodiment an end closure having occluding surfaces is provided for use in connection with conventional perforated fusion cages so as to establish desired zones or patterns of occluded apertures.

WO 2004/008999 A1

INTERBODY SPINE FUSION CAGE

BACKGROUND OF THE INVENTION

Technical Field:

This invention is directed to improved devices for facilitating the fusion of vertebral bone structure, which devices can be inserted either anteriorly or posteriorly into the spine.

Background:

Chronic back problems cause pain and disability for a large segment of the population. In many cases, such problems are attributable to relative movement between vertebrae in the spine. Spinal surgery includes procedures to stabilize adjacent vertebrae. Common stabilization methods often involve fusing adjacent vertebrae together.

Fusion techniques include removing disc material which separates the vertebrae and impacting bone into the disc area. The impacted bone fuses with the bone material of the two adjacent vertebrae to thereby fuse the vertebrae together. In a further advance in the art, spinal implants have been developed to increase the probability of a successful fusion. Such devices generally comprise a hollow cylindrical cage into which bone growth inducing substances, such as bone chips or bone slurry, may be placed. The cage wall has holes extending radially therethrough, typically throughout the entire cage surface. The combination of the cage and bone growth inducing substance facilitates arthrodesis between the adjacent vertebral bone structures. Fusion cages in both a threaded and non-threaded form have come into wide use in the last several years. Such cages are inserted either anteriorly or posteriorly into the spine in the intervertebral disc space to fuse the adjacent vertebrae as aforedescribed and to decompress neural elements.

With the continued development of techniques for achieving spinal fusion through the use of spine fusion cages, there has also been developed new materials to augment the fusion process. In the older method, the patient's own bone, or cadaver bone, was used in the cage to promote bony fusion. Newer biologic materials have now been discovered that greatly augment the fusion process and in some cases make using the patient's own bone unnecessary.

However, with the utilization of the newer biologic materials there has arisen a significant problem. When bone growth accelerants, such as bone morphogenic proteins,

are used in cages of existing design there is risk of inducing the growth of bone around and into sensitive neural tissues. This is especially the case when a posterior approach is utilized to implant the fusion cage, as bony overgrowth in this direction may impinge on spinal nerve roots. It accordingly should be appreciated that there is a need for a fusion cage designed to be used with such biologic materials to prevent bone growth from impinging on neural tissue.

It is thus an object of the present invention to provide an improved spine fusion cage which prevents the overgrowth of bone around and into sensitive areas of neural tissue.

It is another object of the invention to provide a spine fusion cage having a feature whereby a surgeon may selectively occlude holes in the cage wall to prevent bone growth therethrough.

A further object of this invention is to provide a novel closure for spine fusion cages which can be used with presently available fusion cages in preventing bone growth into undesirable areas.

SUMMARY OF THE INVENTION

In accordance with one embodiment of the present invention there is provided a novel spine fusion cage which can be inserted into an intervertebral disc space using either a posterior or anterior approach and which prevents overgrowth of bone around or into neural tissue. Growth of bone into sensitive areas is prohibited by providing the cage with various zones wherein the cage wall is either perforated or non-perforated. A cage body is provided having a posterior end and an anterior end and defining an internal cavity and a longitudinal axis. The cage body has an outer surface and a plurality of radial apertures extending through the outer surface in communication with the internal cavity in a preselected pattern. Preferably, there is a first non-perforated zone extending from the posterior end of the cage a preselected length toward its anterior end, second and third non-perforated zones on the lateral sides of the cage extending in opposing relation from the first zone further toward the anterior end, and two opposed perforated zones oriented so that upon insertion of the device the perforated zones will be adjacent the vertebral bodies to be fused to allow bone growth across the vertebral interspace. Each

end of the cage is provided with a non-perforated closure. In this manner bone growth is prevented in areas adjacent the non-perforated zones when the fusion cage is in place.

In accordance with another embodiment of the present invention there is provided a novel spine fusion cage which provides for the selective occlusion of apertures in the cage wall so as to prevent the growth of bone in undesired directions. As an example, there is provided an inventive cage having outer and inner cage elements. An outer cage body having a posterior end and an anterior end defines an internal cavity. A plurality of radial apertures extend through the outer surface of the outer cage body to communicate with the internal cavity in a pattern covering a substantial portion of the outer surface of the cage body. An inner cage body is disposed within the internal cavity of the outer cage body and is positioned as to form an annulus between the inner wall surface of the outer cage body and the outer wall surface of the inner cage body. The inner cage body likewise has a plurality of radial apertures extending through its outer surface so as to establish communication with the annulus and the outer surface of the outer cage. An end closure means having occluding surfaces suitable for introduction into the annulus between the outer and inner cages serves to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the outer cage body, thereby obstructing bone growth in undesired directions.

In still another embodiment there is provided an end closure means for effecting the closure of the posterior end of a fusion cage while establishing a desired occlusion pattern of apertures in the wall of the fusion cage. The closure means comprises a non-perforated sealing member to effect the closure of the posterior end of the internal cavity of the fusion cage and one or more occluding surfaces extending from the sealing member essentially parallel to the longitudinal axis of the fusion cage so as to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the cage body.

In additional embodiment, a cage body is provided that has a posterior end and an anterior end and defines an internal cavity. The cage body further has an outer surface and a plurality of apertures extending through the outer surface in communication with the internal cavity, wherein the outer surface has a preselected pattern of perforated and non-perforated zones. A first end closure is secured at a first end of said cage body. A

second end closure is provided that has an orifice therein. The second end closure is secured at a second end of the cage body. At least one of the first end closure and the second end closure is removable so as to provide access to the internal cavity. A plug is located in the orifice that is capable of being penetrated by a syringe needle for administering a bone growth accelerant to said internal cavity. Preferably, a carrier, such as a sponge, receives the bone growth accelerant. By using this approach, chances for misapplication of bone growth material are greatly diminished.

A better understanding of the present invention, its several aspects, and its advantages will become apparent to those skilled in the art from the following detailed description, taken in conjunction with the attached drawings, wherein there is shown and described the preferred embodiments of the invention, simply by way of illustration of the best mode contemplated for carrying out the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 anatomically illustrates a bilateral posterior insertion of two inventive cylindrical spine fusion cages to achieve fusion across the L5/S1 disc space.

FIG. 2 is an exploded perspective view of an embodiment of an inventive cage having preselected perforated and non-perforated zones on its outer surface.

FIG. 3 is a perspective view taken along line 3-3 of FIG. 2.

FIG. 4 is a sectional view taken along line 4-4 of FIG. 2.

FIG. 5 is perspective view of an embodiment of an inventive cage having outer and inner cage elements.

FIG. 6 is a sectional view taken along line 6-6 of FIG. 5.

FIG. 7 is a perspective view of an end closure for use in connection with the cage of FIG. 5.

FIG. 8 a top sectional view of the cage of FIG. 5 including the end closure of FIG. 7.

FIG. 9 is an exploded side view of a conventional fusion cage modified to utilize an inventive end closure means to selectively occlude certain apertures in the outer surface of the cage.

FIG. 10 depicts the partial insertion of the inventive closure means into the cage

of FIG. 9.

FIG. 11 depicts the full insertion of the inventive closure means into the cage of FIG. 9.

FIG. 12 is top sectional view of a modified conventional cage including an inventive end closure means.

FIG. 13 is an exploded perspective view of an embodiment of an inventive cage having an end cap and an injection port.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Several types of conventional spine fusion cages have been designed, such as those described by Bagby, Brantigan and Ray, respectively, in *Athrodesis by the Distraction-Compression Method Using a Stainless Steel Implant*, Orthopaedics 1988, Vol. 11:931-4; *A Carbon Fibre Implant to Aid Interbody Lumbar Fusion*, Spine 1991, 16 (Suppl):S277-82 (with Steffee and Geiger); and *Threaded Titanium Cages for Lumbar Interbody Fusions*, Spine 1997, 22:667-80; and as described in the patent art, for example, in U.S. Patent Nos. 4,501,269; 5,055,104; 5,571,192; 5,702,449; 5,876,457; 5,906,616; 5,976,187; 5,980,522; 6,010,502; 6,015,436; and 6,039,762. Each of the foregoing publications and patents is incorporated herein by reference.

Such devices provide for a relatively simple and effective technique for implementing lumbar interbody fusion by correcting any existing mechanical deformity of the spine while providing stability and a good environment until successful arthrodesis is obtained. These cage devices are hollow and are positioned between the articulating vertebrae, where they support and immobilize the joint as well as contain the growth of the bone graft that is packed into the internal cavity of the device.

Anterior lumbar interbody fusion (ALIF) and posterior lumbar interbody fusion (PLIF) are two commonly adopted approaches for grafted lumbar interbody fusion with augmentation via a spine fusion cage. ALIF is performed through a retroperitoneal or transperitoneal approach with extensive discectomy followed by the placement of one or more cages in the vertebral interspace. In PLIF, partial or complete laminectomy and facetectomy is followed by posterior discectomy and the placement of one or more cages in the vertebral interspace. FIG. 1 is illustrative of a bilateral posterior insertion of two

inventive cylindrical spine fusion cages **20** to achieve fusion across the L5/S1 disc space. The cages **20** are secured far enough apart from each other (by a few millimeters) to avoid contact and potential back-threading. It should be understood that the fusion cages of this invention can be installed in their operative positions via either the anterior or posterior approaches; however, the posterior approach is the most dangerous in regards for bony overgrowth impinging on neural tissue particularly when the cage is used along with bone growth inducing materials.

The inventive cages **20** promote bony fusion by holding adjacent levels immobile and by allowing bone to grow only into the vertebral bodies an away from the spinal canal and nerve roots. Designs that do not control direction of growth are undesirable for use with biologic bone growth accelerants to the extent unchecked bony overgrowth may impinge upon neural tissues. Through the present invention there are provided designs for spine fusion cages which prevent bone growth around and into sensitive areas of neural tissue.

Referring now to FIGS. 2-4, and in accordance with one embodiment of the present invention, there is provided an inventive spine fusion cage **20** wherein growth of bone into sensitive areas is prohibited by providing the cage with various zones or areas wherein the cage wall is either perforated or non-perforated. A cage body **22** is provided having a posterior end **24** and an anterior end **26** and defining an internal cavity **28** and a longitudinal axis **30**. The cage body **22** is typically between 20-25 mm in length and may be of a variety of diameters (if cylindrical) and heights. The cage body **22** has an outer surface **32** and a plurality of radial apertures **34** extending through the outer surface **32** in communication with the internal cavity **28** in a preselected pattern. Preferably, there is a first non-perforated zone **36** extending from the posterior end **24** of the cage body **22** a preselected length, preferably 5-10 mm, toward its anterior end **26**, second and third non-perforated zones **38**, **40** on the lateral sides of the cage body **22** extending in opposing relation from the first zone **36** further toward the anterior end **26**, and two opposed perforated zones **42**, **44** oriented cephalad (or to the superior side) and caudad (or to the inferior side) so that upon insertion of the device the perforated zones **42**, **44** will be adjacent the vertebral bodies to be fused to allow bone growth across the vertebral interspace. Each end **24**, **26** of the cage body **22** is provided with a non-perforated

closure. In the illustrated embodiment, the anterior end **26** is closed by an integral non-perforated end wall **46**, while there is provided a removable end cap **48** securable, by threaded attachment, friction fit or otherwise, to the posterior end **24** of the cage body **22**. The end cap **48** may be provided with a recess **50** for receiving an insertion tool, for example if the end cap is made to threadably connect to the cage body, and there is preferably provided on the top of the end cap **48** a line score **52** for aiding proper orientation of the device in the vertebral interspace.

The cage body **22** may be provided with threads **54**, projections, ridges, protrusions, barbs, spurs or other insertion means to aid in placement of the cage within the interbody area. The anterior end **26** can be rounded in order to facilitate the insertion of the cage **20** relative to one or more bone structures. The cage **20** may be made of surgical steel, titanium or other acceptable implantable materials. Typically, the cage **20** is countersunk into the vertebral interspace with the end cap **48** in place by using an insertion tool (not shown) to screw the cage **20** into position. Once the cage is properly aligned, the end cap **48** is removed so that bone growth inducing material can be packed into the internal cavity **28** of the cage body **22**, whereupon the end cap **48** is tightly replaced.

As can now be appreciated, the inventive cage **20** prevents bone growth into areas adjacent the non-perforated zones when the fusion cage is in place. Because the posterior 5-10 mm of the cage is non-perforated, including, importantly, the end cap, bony overgrowth is inhibited in areas immediately adjacent the posteriorly located neural tissues. In similar fashion, lateral overgrowth of bone is impeded by the second and third non-perforated zones. Desired growth through the vertebral interspace, however, is facilitated via the perforated zones.

It should be understood to be within the ordinary skill of one in the art to modify the placement of the various perforated and non-perforated zones as warranted by orthopaedic considerations to achieve desired bone growth and preclude unwanted bone growth. It is also within the ordinary skill of one in the art to modify the aforedescribed device for anterior insertion procedures by providing a removable end cap on the anterior end of the cage body and reversing the thread direction on the outside surface of the cage body.

As mentioned above, it is also advantageous for a surgeon to have the ability to selectively occlude apertures in the cage wall to prevent bone growth in undesired directions. Now referring to FIGS. 5-8, to achieve this object, and in accordance with another embodiment of the present invention, there is provided a spine fusion cage **120** having an outer cage body **122** with a posterior end **124** and an anterior end **126** and defining an internal cavity **128** and a longitudinal axis **130**. The outer cage body **122** has an outer surface **132** and a plurality of radial apertures **134** extending through the outer surface **132** in communication with the internal cavity **128** in a pattern covering a substantial portion of the outer surface **132** of the cage body **122**. An inner cage body **136** into which is placed bone growth inducing substances is disposed within the internal cavity **128** of the outer cage body **122** and is positioned as to form an annulus **138** between the inner wall surface **140** of the outer cage body **122** and the outer wall surface **142** of the inner cage body **136**. The inner cage body **136** likewise has a plurality of radial apertures **144** extending through its outer surface **142** so as to establish communication with the annulus **138** and the outer surface **132** of the outer cage body **122**. A solid end closure **146** having opposed occluding surfaces **148, 150** suitable for introduction into the annulus **138** serves to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the outer cage body **122**, thereby obstructing bone growth in undesired directions.

More specifically, as shown in FIG. 7 end closure **146** is comprised of a non-perforated cap or closure means **152** having occluding surfaces **148** and **150** extending therefrom. Such surfaces may be of sufficient length to extend to the bottom of the cage member **120** as shown in FIG. 5 or may be of a more limited length so as to occlude only a portion of the apertures **134** in the outer cage body **122**. The end closure **146** may be constructed so as to provide a top circumferential crown portion **154** and between the occluding surfaces **148, 150** a shoulder **156** which may engage a rib means **158, 160** as shown in FIG. 8 to act as a longitudinal stop and to limit the degree of rotation which can be made by occluding surfaces **148, 150** so as to maintain the selected occlusion pattern. When positioned within the annulus **138** of the fusion cage **120**, the occluding surfaces **148, 150** serve to close openings in the posterior end of the cage **120** as well as to occlude openings which are in a lateral position so as to effect bone growth through the apertures

in the caudal and cephalad directions when placed in the desired position between two vertebrae. Various interchangeable forms of end closures may be provided, for example having differently shaped and dimensioned occluding surfaces, so as to provide for the surgeon a selection which meets objectives according to various orthopaedic exigencies. It is also within the scope of this invention that the shape and dimensions of the occluding surfaces may be modifiable by the surgeon, such as if the occluding surfaces comprise a surgical plastic adapted to be cut or trimmed to achieve a desired configuration. In this manner, a cage possessing a full pattern of apertures can be used as a "universal" cage in combination with one of a wide selection of end closures or a modifiable end closure to achieve any desired patterned of perforation.

The end closure **146** can be threaded or otherwise designed to effect the closure of the posterior end of the cage **120** and may be provided with securing means such as square or hex-shaped recess **162** which can be used with a socket wrench to tightly position the end closure **146** in the posterior end of the fusion cage **120**. In complementary fashion, threads may be provided at the posterior end of the cage **120** to receive a threaded end closure **146** or it can be so adapted that the end closure **146**, when not threaded, can be simply snapped into place to effect the desired closing of the fusion cage **120**.

A thread **164** may be provided as part of the outer surface **132** of the fusion cage **120**. Such a thread can be replaced with a plurality of discrete threads or a plurality of projections, ridges, protrusions, barbs or spurs and be within the spirit and scope of the invention.

In assembly of the fusion cage of this embodiment of the invention, following introduction of the selected biologic material into the internal cavity **128** within the inner cage body **136**, the annulus **138** remains clear so as to easily accept end closure **146** within the annulus **138** while the biologic materials are retained in the internal cavity **128**. Through the dimensioning, shaping and rotation of occluding surfaces **148**, **150** there is achieved an occlusion of apertures so as to define the desired pattern of apertures through which bone growth is to be permitted.

In keeping with the teachings of the present invention, there is further provided a novel closure for conventional spine fusion cages which can be used with little or no

modification to presently available fusion cages in preventing bone growth into undesirable areas. This embodiment involves providing a means for the occlusion of selected apertures in currently available fusion cages, such as to those commonly referred to as Brantigan, BAK and Ray cages, so that bone growth is directed only toward the vertebral bodies and away from the spinal canal and nerve roots.

Making reference now to FIGS. 9-11, there is illustrated an end closure **220** for effecting the closure of the posterior end **222** of a conventional fusion cage body **224** while establishing a desired occlusion pattern of apertures in the wall of the cage body **224**, which cage possesses apertures **226** substantially entirely thereabout. The end closure **220** comprises a non-perforated sealing member **228** to effect the closure of the posterior end **222** of the cage body **224** and one or more occluding surfaces **230, 231** extending from the sealing member **228** essentially parallel to the longitudinal axis **230** of the cage body **224** so as to establish one or more desired zones or patterns of occluded apertures amongst the plurality of apertures in the cage body **224**. Reference is made to the disclosure provided above with respect to the aforedescribed end closure **146,** which disclosure is equally applicable to end closure **220** and further recitation is believed unnecessary. Suffice it to say that the prior described end closure **146** may be made adaptable to conventional fusion cages so as to achieve the objectives of the present invention.

As depicted in FIG. 12, if desired the conventional type of fusion cage can be so modified as to provide ribs **232, 234** in association with the inner surface of the posterior end of the cage according to the teachings herein. FIG. 12 provides a top view of the fusion cage of FIG. 11 along the line 12-12 which shows the placement of the ribs **232** and **234** to accommodate occluding surfaces **230, 231** of the end closure **220**.

Referring now to FIG. 13, an exploded view of an embodiment of an inventive cage **300** is shown having an end cap **302** and an end cap **304** having an orifice **306**. Orifice **306** is preferably sealed with a plug **308**, e.g. a silicone plug or a plug of another material capable of being penetrated by a syringe needle. A carrier **310** for bone growth accelerants, such as bone morphogenic proteins, is located in the interior of cage **300**. A preferred carrier **310** is a sponge type material. In use, the cage **300** is desirable because cage **300** may be located within a patient prior to loading cage **300** with bone

growth accelerants. Locating cage **300** prior to loading the bone growth accelerant prevents bone growth accelerant from inadvertently contacting areas of the patient that are not intended to experience bone growth. After the cage **300** is located, bone growth accelerant may be carefully administered via a syringe needle, which is pushed through plug **308**. Once the syringe needle has penetrated plug **308**, bone growth accelerant may be delivered to the carrier **310**, e.g. sponge. In this way, the risks associated with locating a cage **300** filled with bone growth accelerant are minimized.

While the invention has been described with a certain degree of particularity, it is understood that the invention is not limited to the embodiment(s) set for herein for purposes of exemplification, but is to be limited only by the scope of the attached claim or claims, including the full range of equivalency to which each element thereof is entitled.

WHAT IS CLAIMED IS:

1. An interbody spine fusion cage for promoting fusion between adjacent bone structures, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface and a plurality of apertures extending through the outer surface in communication with the internal cavity, the outer surface comprising a preselected pattern of perforated and non-perforated areas, wherein, upon implantation, a perforated area is in contact with an adjacent bone structure while all areas of the cage body not in contact with adjacent bone structure are imperforate; and

a non-perforated end closure at each end of said cage body, at least one of the end closures being movable so as to provide access to the internal cavity.

2. The cage according to claim 1, further comprising an upper perforated area for locating adjacent an upper bone structure to be fused and a lower perforated area for locating adjacent a lower bone structure to be fused, wherein said upper perforated area and said lower perforated area are separated exclusively by non-perforated areas.

3. The cage according to claim 1, wherein:

said non-perforated zones are on lateral sides of the cage and extend in opposing relation from the posterior end toward the anterior end; and

said perforated areas comprise two opposed perforated areas oriented so that upon insertion the perforated areas are adjacent the bone structures to be fused.

4. An apparatus for insertion into a vertebral interspace between adjacent vertebral bodies to facilitate arthrodesis between bone structures of the adjacent vertebral bodies while preventing bony overgrowth toward neural elements, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface and a plurality of apertures

extending through the outer surface in communication with the internal cavity in areas of the outer surface which, upon implantation of the apparatus, allow for arthrodesis between the bone structures;

wherein areas of the cage body directed toward neural elements upon implantation of the apparatus are not in communication with the internal cavity so as prevent bony overgrowth toward the neural elements.

5. The apparatus of claim 4, further comprising:

means on the cage body for aiding insertion of the cage body between adjacent vertebral bodies.

6. The apparatus of claim 4, further comprising:

a non-perforated removable end cap securable to the posterior end of the cage body.

7. In a body having vertebral bodies defining a central canal, a spinal cord located in the central canal, neural elements branching out from said spinal cord through openings between the vertebral bodies, an arthrodesis facilitating therapeutic combination comprising:

a cage body inserted between the adjacent vertebral bodies, said cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface that forms a periphery of said cage body, said outer surface having at least one aperture formed therein;

a longitudinal occluded area on said cage body, said occluded area for preventing communication between said internal cavity and said outer surface; and

wherein said longitudinal occluded area shields the neural elements from said internal cavity.

8. An apparatus for insertion between adjacent vertebral bodies to facilitate arthrodesis between bone structures of the adjacent vertebral bodies while preventing bony overgrowth toward neural elements, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface that forms a periphery of said cage body, said outer surface having a plurality of apertures formed therein;

wherein one of said posterior end and said anterior end is a non-perforate surface and one of said posterior end and said anterior end is an open end;

an end closure for locating at said open end of said cage body, said end closure having a longitudinal occluding surface for selectively occluding a longitudinal portion of said apertures of said cage body, said longitudinal occluding surface sized to provide an occluded portion of sufficient size to prevent bone growth from impinging on neural tissue when said cage body is inserted between adjacent vertebral bodies.

9. An interbody spine fusion cage for promoting fusion between adjacent bone structures, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface and a plurality of apertures extending through the outer surface in communication with the internal cavity, the outer surface comprising a preselected pattern of perforated and non-perforated zones; and

a non-perforated end closure at each end of said cage body, at least one of the end closures being movable so as to provide access to the internal cavity; and wherein

the preselected pattern comprises at least a first non-perforated zone extending from the posterior end of the cage body for a length of 5-10 mm toward the anterior end of the cage body, wherein said cage body is imperforate except for where said cage body defines at least one opening, said at least one opening is in contact with an adjacent bone structure upon implantation.

10. The cage according to claim 9, wherein the preselected pattern further includes at least a

second non-perforated zone extending from the first zone further toward the anterior end of the cage body on a lateral side of the cage body wherein said second non-perforated zone comprises at least 25% of a circumference of said cage body.

11. The cage according to claim 9, wherein the preselected pattern further includes:

second and third non-perforated zones on the lateral sides of the cage extending in opposing relation from the first zone further toward the anterior end;

two opposed perforated zones oriented so that upon insertion the perforated zones adjacent the bone structures to be fused; and

wherein said second and third non-perforated zones each comprise at least 25% of a circumference of said cage body.

12. An interbody spine fusion cage for promoting fusion between adjacent bone structures, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface and a plurality of apertures extending through the outer surface in communication with the internal cavity;

a non-perforated end closure at each end of said cage body, at least one of the end closures being movable so as to provide access to the internal cavity; and wherein

the movable end closure has at least one aperture occluding surface extending therefrom, the surface being suitable for introduction into the internal cavity to establish a desired pattern of occluded apertures.

13. The cage according to claim 12, further comprising:

a second cage body having a posterior end and an anterior end and being disposed within the internal cavity of the other cage body and so positioned as to form an annulus therebetween, the outer surface of the second cage body having a plurality of radial apertures extending therethrough so as to establish communication with the annulus; and wherein

the occluding surface of the movable end closure being suitable for introduction into the annulus to establish a desired pattern of occluded apertures.

14. End closure means for effecting the closure of the posterior end of a fusion cage while establishing a desired occlusion pattern of apertures in the wall of the fusion cage which comprises:

a first sealing member to effect the closure of the posterior end of the internal cavity of said fusion cage; and

at least one occluding surface extending from the sealing member and essentially parallel to the longitudinal axis of the fusion cage so as to establish a predetermined pattern of occlusion of the apertures in the wall of the fusion cage.

15. The end closure means according to claim 14, further comprising a pair of opposed occluding surfaces so spaced as to occlude laterally positioned apertures along the wall of the fusion cage.

16. An apparatus for insertion into a vertebral interspace between adjacent vertebral bodies to facilitate arthrodesis between bone structures of the adjacent vertebral bodies while preventing bony overgrowth toward neural elements, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface and a plurality of apertures extending through the outer surface in communication with the internal cavity in areas of the outer surface which, upon implantation of the apparatus, allow for arthrodesis between the bone structures;

wherein areas of the cage body directed toward neural elements upon implantation of the apparatus are not in communication with the internal cavity so as prevent bony overgrowth toward the neural elements.

17. The apparatus of claim 16, further comprising:

means on the cage body for aiding insertion of the cage body between adjacent vertebral bodies.

18. The apparatus of claim 16, further comprising:

a non-perforated removable end cap securable to the posterior end of the cage body.

19. An arthrodesis facilitating therapeutic combination comprising:

adjacent vertebral bodies defining a central canal;

a spinal cord located in said central canal;

neural elements branching out from said spinal cord through openings between said vertebral bodies;

a cage body inserted between said adjacent vertebral bodies, said cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface that forms a periphery of said cage body, said outer surface having at least one aperture formed therein;

a longitudinal occluded area on said cage body, said occluded area for preventing communication between said internal cavity and said outer surface; and

wherein said longitudinal occluded area shields said neural elements from said internal cavity.

20. An apparatus for insertion between adjacent vertebral bodies to facilitate arthrodesis between

bone structures of the adjacent vertebral bodies while preventing bony overgrowth toward neural elements, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface that forms a periphery of said cage body, said outer surface having a plurality of apertures formed therein;

wherein one of said posterior end and said anterior end is a non-perforate surface and one of said posterior end and said anterior end is an open end;

an end closure for locating at said open end of said cage body, said end closure having a longitudinal occluding surface for selectively occluding a longitudinal portion of said apertures of said cage body, said longitudinal occluding surface sized such that said occluded longitudinal portion of said apertures have a width of at least 1/4 of the periphery of said cage body, thereby providing an occluded portion of sufficient size to prevent bone growth from impinging on neural tissue when inserted between adjacent vertebral bodies.

21. An interbody spine fusion cage for promoting fusion between adjacent bone structures, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity, the cage body further having an outer surface and a plurality of apertures extending through the outer surface in communication with the internal cavity, the outer surface comprising a preselected pattern of perforated and non-perforated zones; and

a first end closure at a first end of said cage body;

a second end closure having an orifice therein, said second end closure at a second end of said cage body, at least one of said first end closure and said second end closure being removable so as to provide access to the internal cavity; and

a plug located in said orifice, said plug capable of being penetrated by a syringe needle for administering a bone growth accelerant to said internal cavity.

22. The interbody spine fusion cage according to claim 21 wherein:

the preselected pattern comprises at least a first non-perforated zone extending from the posterior end of the cage body for a length of 5-10 mm toward the anterior end of the cage body and at least one perforated zone positioned upon the outer surface of the cage body so as to be juxtaposed one of the bone structures upon implantation.

23. An apparatus for insertion into a vertebral interspace between adjacent vertebral bodies to facilitate arthrodesis between bone structures of the adjacent vertebral bodies, comprising:

a cage body having a posterior end and an anterior end and defining an internal cavity;

an end cap located at one end of said cage body, said end cap having an orifice therein; and

a plug located in said orifice, said plug capable of being penetrated by a syringe needle.

24. The apparatus according to claim 23 further comprising:

a carrier material located in said internal cavity for receiving bone growth accelerant through said plug.

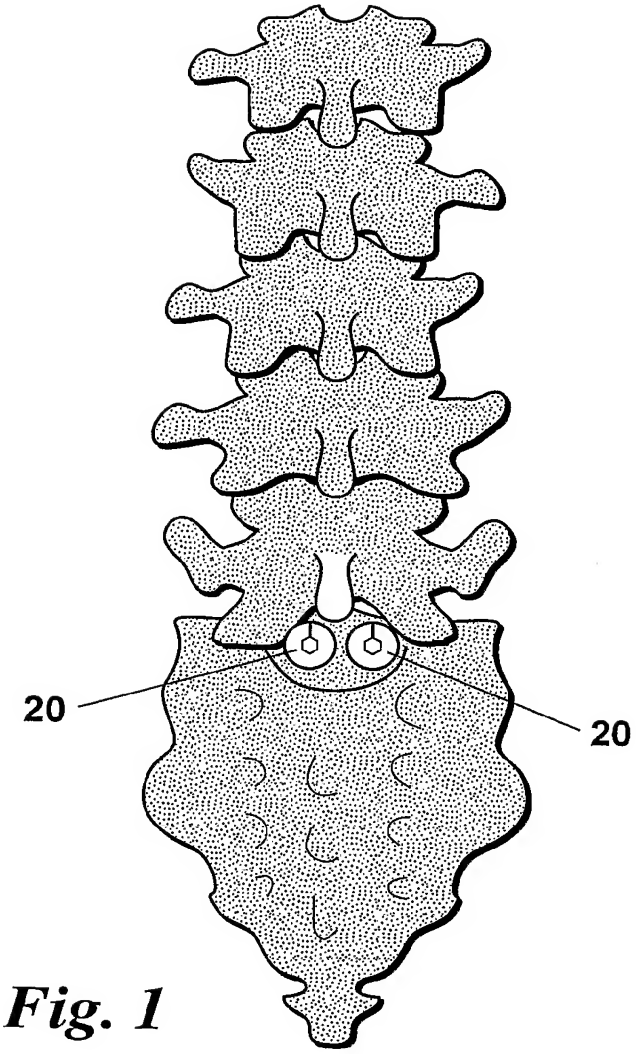

Fig. 1

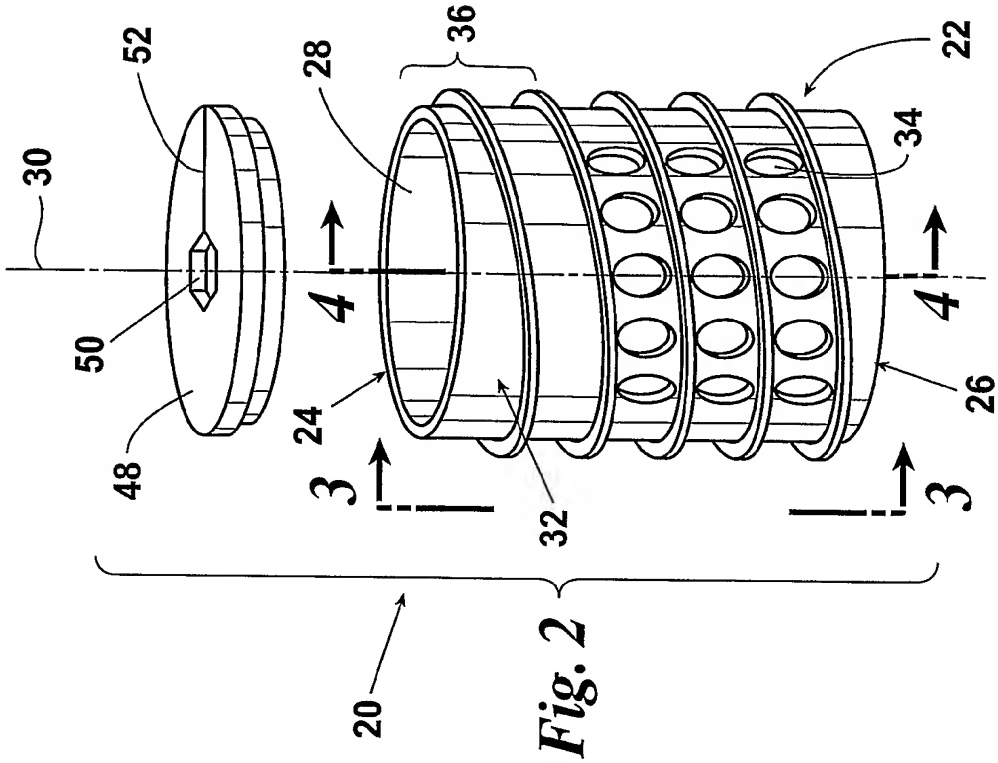

Fig. 2

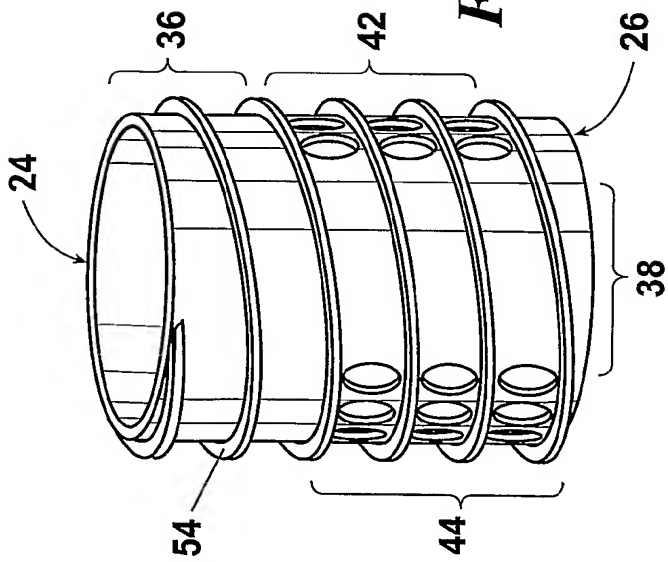

Fig. 3

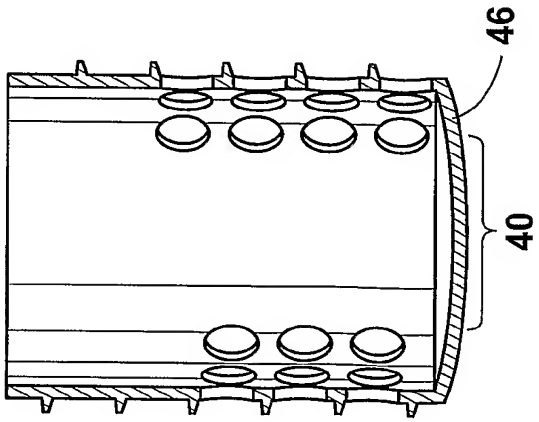

Fig. 4

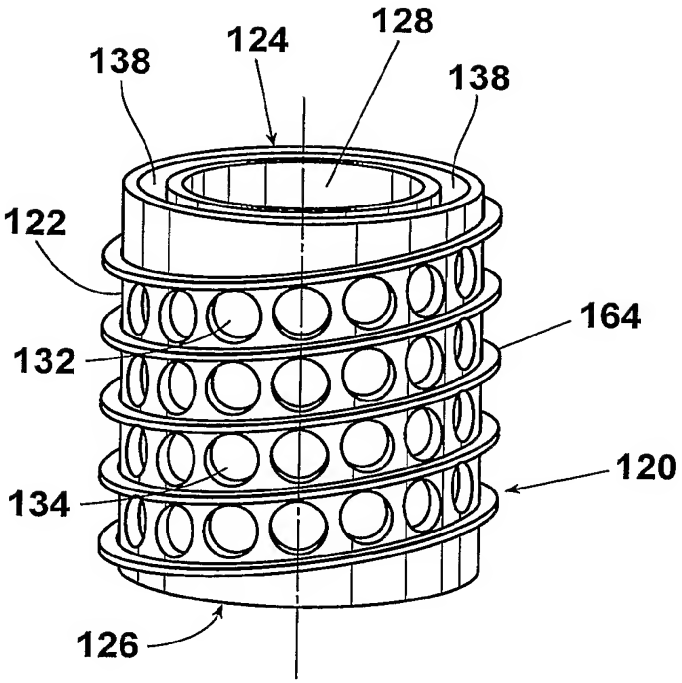

Fig. 5

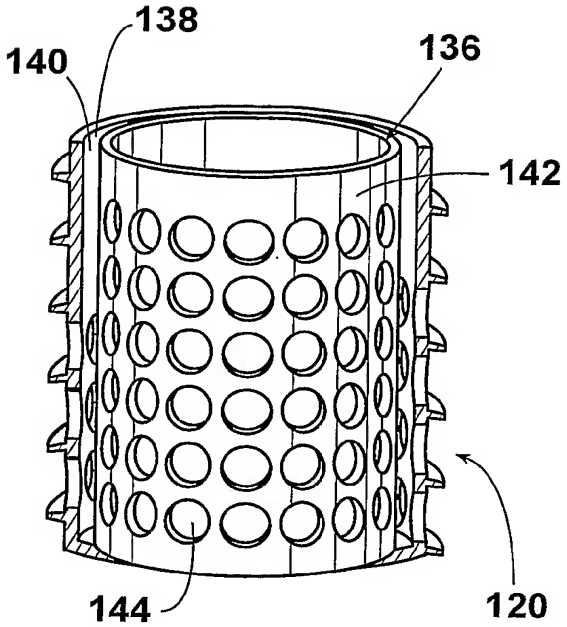

Fig. 6

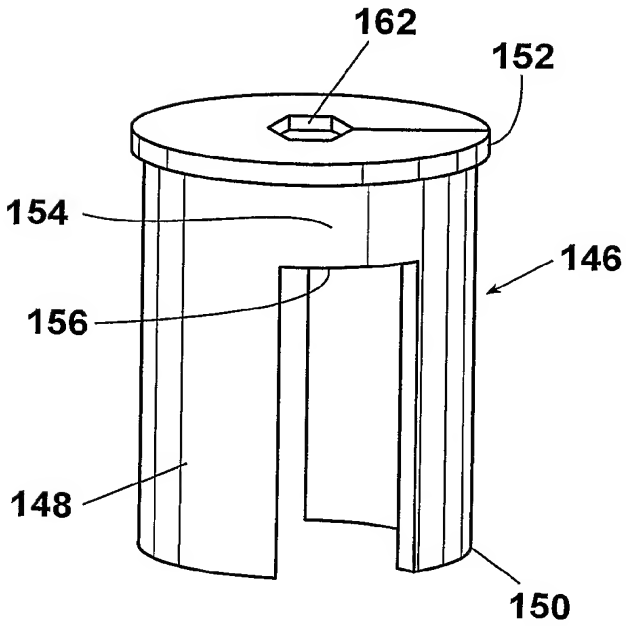

Fig. 7

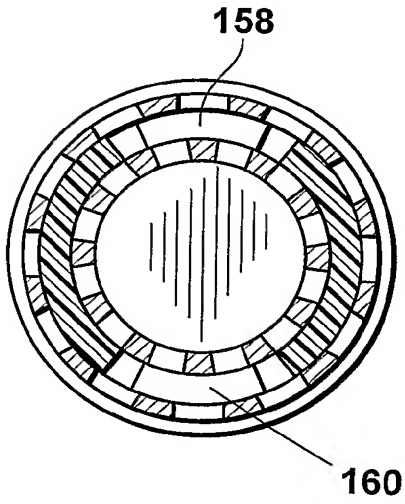

Fig. 8

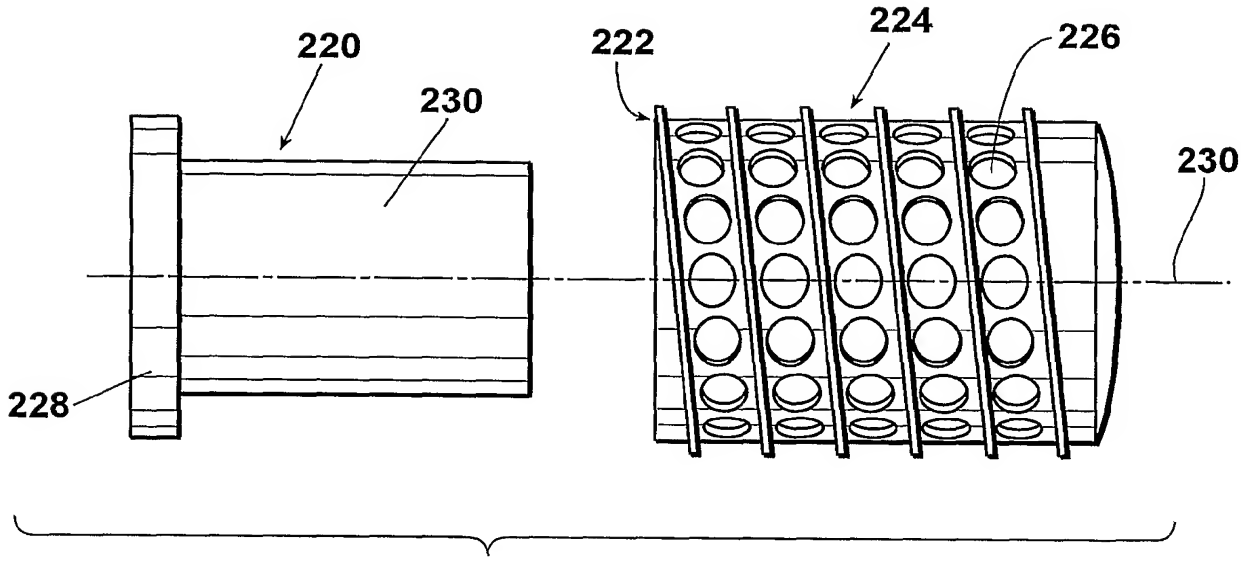

Fig. 9

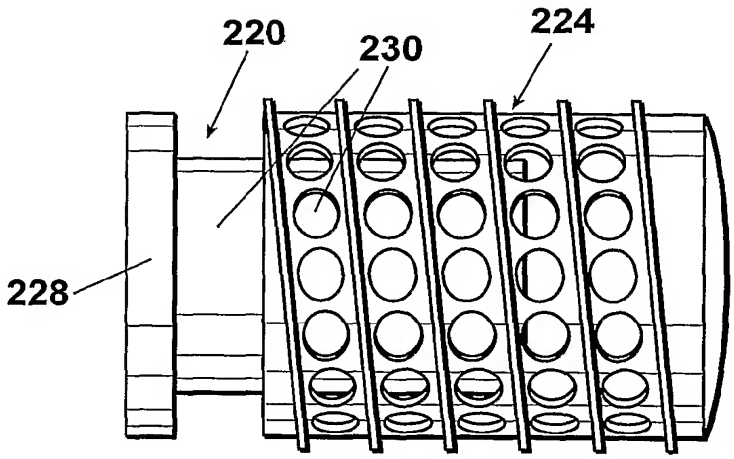

Fig. 10

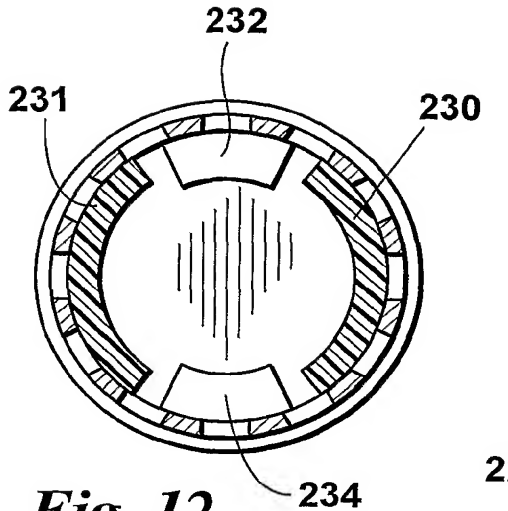

Fig. 12

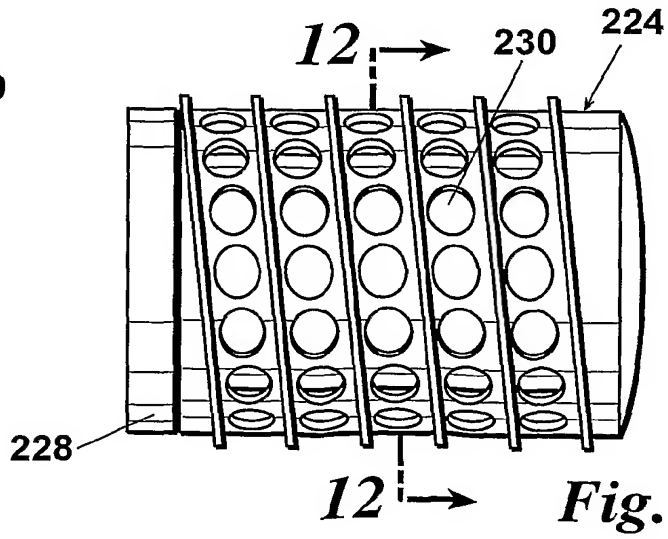

Fig. 11

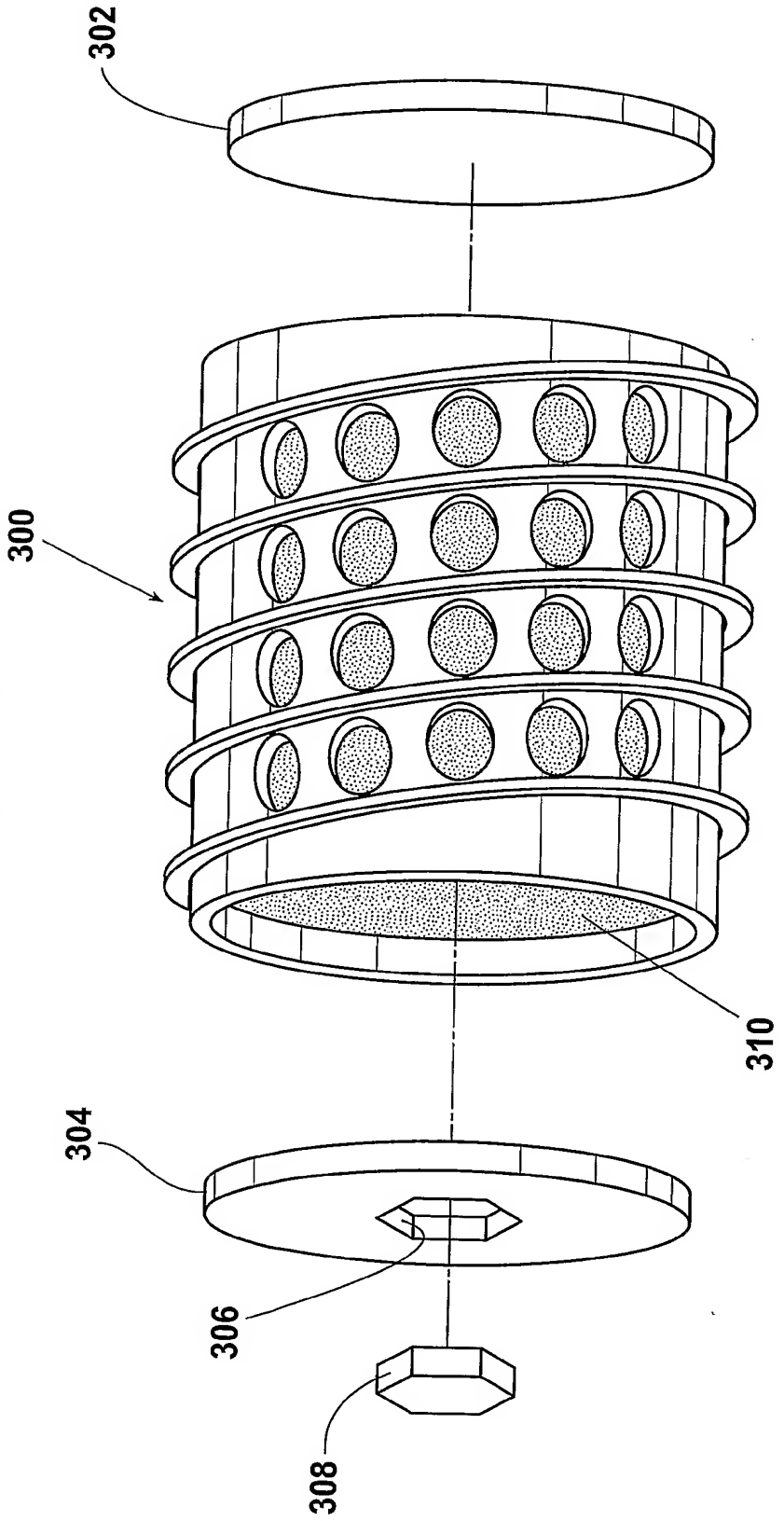

Fig. 13

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/23262

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44 A61F2/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2001 032018 A1 (MCDONNELL CHRISTOPHER ET AL) 18 October 2001 (2001-10-18) figures 3,9-11 paragraphs [0028] - [0032] -----	1-7, 9-11, 16-19
X	EP 0 716 840 A (SURGICAL DYNAMICS INC) 19 June 1996 (1996-06-19) figures 1,4,5,7-10,20 column 5, line 30 - line 62 column 11, line 30 - line 62 -----	1-7, 9-11, 16-19
X	US 5 683 394 A (RINNER JAMES A) 4 November 1997 (1997-11-04) figures 1,5 column 3, line 16 - line 65 -----	1-7, 9-11, 16-19
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 March 2003	10. 09. 2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Stach, R.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 02/23262

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 760 355 A (SCHRAYER SERGE) 11 September 1998 (1998-09-11) claims 1,2,10; figures 1,4-7	4-7, 16-19
A	-----	1-3,9-11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/23262

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-7,9-11,16-19

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 02/23262

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-7, 9-11, 16-19

An interbody spine fusion cage comprising:

a cage body defining an internal cavity, the cage body having an outer surface comprising a preselected pattern of perforated and non-perforated areas, wherein upon implantation, a perforated area is in contact with an adjacent bone structure while all areas of the cage body not in contact with adjacent bone structure are imperforated.

(Problem: preventing bony overgrowth from the implant toward the neural elements)

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2. claims: 8, 12, 13, 20

An interbody spine fusion cage comprising:

a cage body defining an internal cavity and having an outer surface with a plurality of apertures formed therein, one of the anterior or posterior end of the cage is a non-perforated surface and one of the said ends is an open end,
an end closure for locating at said open end of said cage body, the end closure having a longitudinal occluding surface for selectivly occluding a longitudinal portion of said apertures to prevent bone growth from impinging on neural tissue when said cage body is inserted between adjacent vertebrae.

(Problem: facilitating the implantation of the fusion cage in cases where bone growth into certain areas around the implant should be prevented)

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3. claims: 14, 15

End closure means for effecting the closure of the posterior end of a fusion cage while establishing a desired occlusion pattern of apertures in the wall of the fusion cage which comprises:
first sealing member to effect the posterior end of the fusion cage; and
at least one occluding surface extending from the sealing member and essential parallel to the longitudinal axis of the fusion cage to establish a predetermined pattern of occlusion of the apertures.

(Problem: occluding certain apertures in the surface of a (any) fusion cage)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

4. claims: 21-24

An interbody spine fusion cage comprising:

a cage body having a posterior and an anterior end, an internal cavity and an outer surface with a preselected pattern of perforated and non-perforated zones; and
a first end closure at a first end of said cage body, a second end closure having an orifice at a second end of said cage body, at least one of said first and said second end closure being removable; and
a plug located in said orifice, the plug being capable of being penetrated by a syringe needle for administering a bone growth accelerant to said internal cavity.

(Problem: administering a drug to the internal closed cavity of an implant via a syringe)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/23262

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Declarations under Rule 4.17:
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations*

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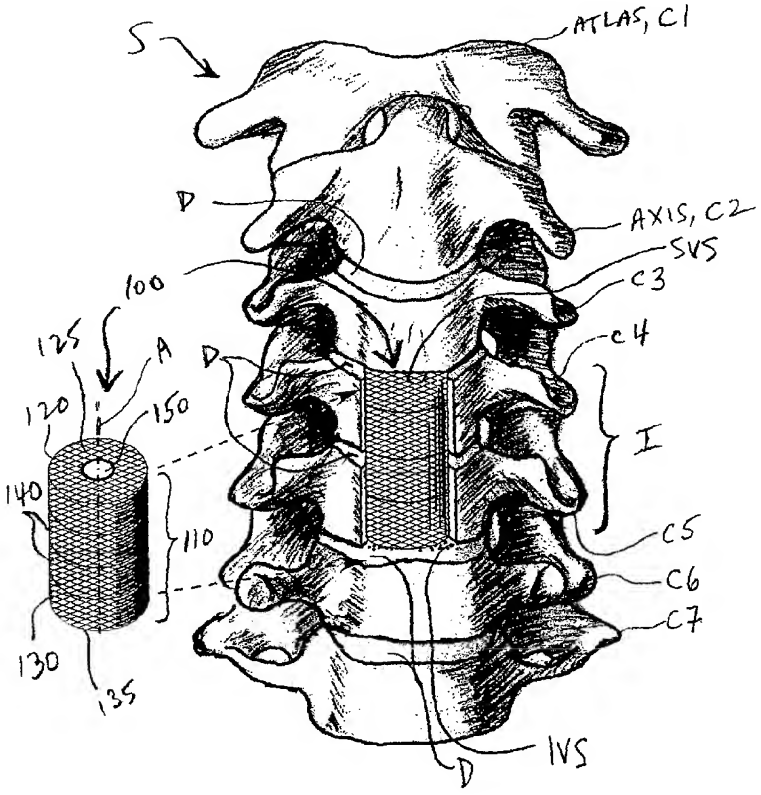
[Continued on next page]

(54) Title: BONE GRAFT DEVICE



(57) Abstract: A bone graft device (100)including a plurality of pseudo-vertebrae (110) that are each formed with a transverse cross-sectional profile sized for implantation in the anterior spinal area. The pseudo vertebrae can be wedge-shaped and are stacked on at least on stanchion that can be centrally positioned or spaced apart. At least one of the plurality of pseudo-vertebrae defines an exteriorly facing sill (125) that engages at least one of the inferior and superior vertebral surfaces (IVS, SVS) to maximize frictional contact between the sill and at least one of the surfaces. Each pseudo-vertebral sill is sized and shaped to be equal to or smaller than the cross-section of the vertebral bodies (C,T) defining the superior and inferior vertebral body surfaces so as to not invad the vertebral channel of the spinal column (S) when the bone graft device (100) is introduced into a resected area.

WO 2004/024038 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

TECHNICAL FIELD

This invention relates to the field of bone grafts. More specifically, the invention relates to a multimodal bone graft device that incorporates one or a plurality of bone pieces arranged in combination with one or a plurality of cortical bone pieces in new and novel configurations adapted for use in a variety of bone graft applications.

BACKGROUND OF THE INVENTION

A normal human body has hundreds of bones. Collectively, these bones make up the skeleton and the skeletal system. This skeletal system has many functions in the body. One core function of the skeleton is to impart rigidity and definition to the human form. Another function of the skeletal system is to permit movement by acting as load-bearing members, levers, and as attachment anchors for muscles and connective tissues. The skeleton, although responsible for these and other structural functions in the human body, is itself also a dynamic, living organ system.

For example, red blood cells and most immune cells originate and mature in the marrow of bones in a process known to those with skill in the art as hematopoiesis. Furthermore, the mass of a human bone will vary from day to day as calcium stored therein leaches away from bone and into the blood stream and back again as the bone tissues continuously regenerate. Thus, in addition to establishing structural support and movement capabilities, bones also serve as an important reservoir for minerals and especially for calcium, which is an essential mineral that is required for muscle contraction, nerve impulse generation, nerve impulse propagation, and certain enzymatic functions.

The skeleton functions not only dynamically and mechanically as a collective system, but each skeletal bone is an individual tissue that may have a unique structure or function. Individual bones can vary greatly in their size, shape, density, thickness, perfusion, enervation, and other physical and physiological properties. A great deal of this variety stems from or contributes to the disparate functions performed by individual bones. There are many examples of such individual, specialized bone functions. For instance, the skull is actually formed from several smaller bones, that are joined together to protect the brain from damage. The rib cage and the spinal column similarly and respectively protect the thoracic organs and spinal chord, while the lesser bones of the ear facilitate hearing.

The bones of the feet are adapted to bear a much heavier weight and shock load than other bones such as those of the hand, which hand bones contrastingly move with greater degrees of freedom than the foot bones. The bones or vertebrae of the spinal column even have

specialized functions within their ranks: the upper cervical vertebrae are especially adapted for twisting or rotation about a longitudinal axis so that the head can readily turn from side to side. In contrast, the lower thoracic or dorsal and lumbar spinal vertebrae are more limited in their range of relative motion while being capable of supporting much greater loads than the cervical vertebrae. The adaptation and specialization of various bones is not limited to the human animal; Pandas, for example, use one of their wrist bones as an opposable digit, a pseudo thumb of sorts.

To accomplish effectively these diverse functions and tasks, many bones have specialized features. One obvious example of such specialization is the shape of the bones. The skull, the tibia, and the sternum look nothing like each other, because each of these bones is defined to be functionally and geometrically disparate and to accommodate different tissues, organs, and capabilities. In addition to bone shape being highly variable, there is also considerable variation in the cross-sectional density of each bone. Most bones have a generally sponge-like or cancellous interior body portion that while being substantially rigid is less dense than an outer, more dense, and compact layer that is referred to as the cortical rim or layer. Depending upon the load and shock bearing requirements of a given bone, this outer shell can have a widely varying thickness. This outer cortical layer or shell or rim imparts much of the strength to the bone. Relatively thick cortical shells or rims are typical of, for example, the vertebrae of the spinal column, as well as for the bones of the legs, and other bones that carry a high weight or compressive or tensile load. In contrast, the flat bones that are the site of hematopoiesis tend to have relatively increased amounts of the spongy, inner layer of bone known to those having skill in the art as the cancellous layer or cancellous bone. The porosity of the cancellous layer provides an incubation or living space for the developing blood and immune system cells, while the increased perfusion that is typical of cancellous bone brings adequate supplies of food, nutrients, and other factors to these developing cells.

In spite of the diversity of the form and function of various bones, all bones have substantial physiological similarities to each other. For example, bones are typically composed of the same essential materials, regardless of specialized function or shape. A significant portion of bone is organic material, mostly protein-associated glycosaminoglycans and especially collagen, a protein commonly found in connective tissues and in extracellular matrixes. About half of the bone mass is mineral, and the most common bone-associated mineral is a calcium compound that closely resembles hydroxyapetite. Like the rest of the body, bone also contains a significant amount of water.

In addition to composition, bones dissimilar in shape and size usually share other physiological similarities. For example, a thin layer of connective tissue typically covers the

outer surface of the bone. Similarly, a thin, membranous layer lines the interior cavity of the bone. This thin, membranous layer is associated with several bone-producing cell types such as osteogenic cells, osteoblasts, and osteoclasts, for example. Those with skill in the art may know these two layers as the periosteum and the endosteum, respectively.

Another example of physiological similarities shared by various types of bones is vascularization. Blood vessels penetrate and permeate the bone through a series of channels and canals. These channels and canals can vary in location, length, and diameter. Examples of such channels include the canaliculi, haversian canals, osteons, Volkmann's canals, and others. These canals bring blood, nutrients, and other vital factors to and carry away waste from the multitude of cells that live in and that form the bone. One important example of such a bone-dwelling cell is the pluripotent stem cell that can differentiate into and form any of the cells of the blood or immune system. The blood and immune cells themselves also reside, at least for a time, in the bone. Such cells include macrophages, neutrophils, B cells, various T cells, eosinophils, basophils, megakaryocytes (the progenitor of platelets), and red blood cells. There are also varieties of bone-forming cells such as the osteoclasts, osteoblasts, and osteogenic cells mentioned above that live in the bone. Attached to the bones may be various tendons and other connective tissues that cooperate with the bones and any connected muscles to establish the articulation of movement or to secure tissues or organs in place.

Yet another example of shared bone physiology is the specialized structures located at one or both ends of some bones. These specialized structures are adapted to hold a bone in a joint, while at the same time giving some degree of freedom and relative motion to the jointed bones. Examples of this type of arrangement include the bones that form the elbow, knee, shoulder, finger, ankle, foot, vertebral, and similarly movable joints. In addition to these and other physiological similarities, bones also can share developmental similarities. For example, the process of either intramembraneous ossification or endochondral ossification forms the bones, wherein the latter process involves a cartilaginous intermediate that is calcified to form the resulting bone tissue. Fibroblast cells typically lay down a network of collagen fibrils, upon which are deposited the calcium crystals in a mineral form approximating hydroxyapetite.

Aggregates of such calcified fibrils form fibers that then form the bone. The arrangement of the fibers can significantly affect the gross anatomy and function of a bone. For example, fibers can be substantially parallel to each other, perpendicular to each other, may be in a stochastic order, or some combination thereof. The fibers may be arranged in lamellae or can be interwoven. The density of the fibers can also affect the properties of bone. The fibers can be dense and compact, such as in the tough outer rim, shell, or layer of cortical bone, or the fibers

can be loosely arranged and spongy, such as in the inner body of cancellous bone tissue. Further details of the preceding discussion as well as additional information about bone development and physiology can be found in the fourth chapter of the Color Atlas of Histology, second edition, by Leslie P. Gartner and James L. Hiat, Williams & Wilkins, Baltimore, Maryland, USA, 1994.

As can be understood by those skilled in the art, the complexity of bone functions and structures establish a skeletal system having extraordinary capabilities. Yet, as with any highly-refined and precisely engineered system, many possible anomalies can develop and afflict the system that can include disease, degeneration, and failure. Developmental disorders caused by genetic diseases such as osteogenesis imperfecta can cause imperfectly formed or non-functional bones. Even if bones develop correctly, bones can break and fracture and can be susceptible to infections and diseases such as Staphylococcus aureus, which can kill an otherwise healthy bone, possibly necessitating resection, removal, and amputation. Osteoporosis, a degenerative disease common among women as they age, can leave bones brittle and easily broken. Conditions such as spondylolisthesis, pinched or compressed spinal nerves, and degenerative and stenosis inducing intervertebral disc diseases can all cause pain and limitations on possible range of motion. In addition to diseases and disorders, trauma such as that caused by automobile accidents, falls, collisions, heavy loading, and the like can also damage or break a bone and can injure connective and interstitial tissues.

Often, it is possible to correct or limit such maladies. Contagious diseases frequently respond to antibiotic treatment. Diet, exercise, medicaments, and other therapies can sometimes treat or control other disorders. Bone fractures that result from trauma can be routinely set, which term "set," among others, is a term of art that describes the process of holding the broken ends of bone together long enough for them to grow back together. Casts, pins, screws, and braces can also be employed to treat injured or damaged bones. Even with the myriad treatment options available to the patient and practitioner for treating bone diseases and disorders, such treatments alone can be sometimes insufficient or inappropriate. In some cases, additional treatment regimes are indicated and can include resection and removal of damaged bone and connective tissues and grafting of corrective and replacement structures and tissues. Bone grafting can be particularly effective in repairing damaged structures and can include autografts wherein bone is removed from a healthy bone structure in the patient and transplanted to replace damaged bone tissue that has been removed. Allografts can also be obtained from a bone bank and used in similar fashion.

When performing a graft, a surgeon or health care practitioner may have several goals and objectives in repairing an anomalous or injured bone structure. Such goals can include speeding

recovery, healing, and regeneration of replaced tissues, as well as reducing the risk of infection and minimizing post-operative pain, are common to many other surgical procedures. The primary benefit of bone grafting in accelerating healing and regeneration of replaced bone tissue, is that the graft establishes an in vivo template upon which the body can build new bone. The inserted bone graft, while providing interim support during the post-operative healing process, is not the final structural repair to the bone; rather it is a scaffolding of sorts.

If the procedure is successful, the body will deposit calcium, connective, and other tissues onto the implanted graft or scaffold. Over time, living bone will be formed around the inserted piece of bone or graft. Eventually, the graft will be fused into the recipient bone to form one continuous bone. As time continues to pass, eventually the entire graft will be completely scavenged and replaced with regenerated bone in the same way as all bone tissue is continually regenerated. As is known to those skilled in the various related arts, the removal of damaged or injured bone and surrounding tissues exposes extant bone surrounding the site of the bone graft, which signals the proximate and remaining healthy bone that damage exists. The body responds by growing new bone around the site into the template bone graft. This process mimics the response to, for example, a broken bone that fuses back together following the break or facture.

Often, another of the principle aims of the graft is to restore structural integrity and function to a limb, the spine, or other repaired bone tissue. In this case, the practitioner often intends for the graft itself to provide some structural support to the surrounding bone structure immediately upon implant and throughout the subsequent healing, recovery, and regeneration period. The structural support increases as new bone deposits around the graft. A further objective of bone grafting, particularly in the example of back or spinal column procedures, may be to relieve nerve root compression, reverse stenosis, and to replace damaged vertebral and disc elements, which can in turn reduce or ideally eliminate pain. Such spinal procedures can also further include, for example, the fusion of lower back vertebrae to alleviate pain and discomfort. In other instances, another aim of the bone graft procedure may be cosmetic in nature, such as the graft-mediated reconstruction of a jaw or cheekbones.

To help accomplish these and other surgical objectives, several permutations of grafting are possible. In one embodiment, a surgeon removes tissue from the patient and then transplants the tissue in a new location on that same patient. Such a graft is often referred to as an autograft to those with skill in the art. Donor material obtained from another individual that is genetically identical to the recipient is often referred to as an isograft, which is mostly just as preferable as an autograft. A surgeon might perform an auto- or isograft on, for example, a burn victim. In the case of a burn victim, the surgeon can remove undamaged and or donor skin from the back,

buttocks, or another inconspicuous area and then the surgeon can graft that skin onto a burned or otherwise badly damaged area of skin. Autografts and isografts such as skin grafts offer several advantages over other forms of graft. One important advantage is a decreased chance of disease transmission; since the patient receives their own tissue they are not likely to contract any new diseases from that tissue. Another important advantage of an auto- or isograft is that immunological rejection of the tissue is not an issue, since in a healthy person the immune system tolerates its own tissues. An additional advantage of a bone auto- or isograft is that the fresh, living bone readily supports the deposition of new bone and therefore increases the chances of a successful graft procedure.

In spite of these and other advantages, it is often not possible, convenient, or desirable for the surgeon to perform an auto- or isograft. This limitation is especially pronounced in the case of a bone auto- or isograft, where a surgeon excises a piece of bone from a healthy bone such as the pelvis proximate to the iliac crest and then implants that piece of bone elsewhere in the patient. This procedure usually requires two incisions and therefore exposes the patient to twice the risk of surgical infection. The site from which the bone is removed can be very painful during recovery and can result in restricted mobility. Furthermore, it may be impossible to remove a suitably sized or dimensioned bone piece without compromising the integrity or function of the donor bone. As a result of such limitations, surgeons often perform a second type of graft known to those with skill in the art as an allograft.

An allograft is substantially similar to an autograft or isograft, except that the allograft is obtained from another individual of the same species. In the case of a bone allograft, the donor is usually a recently deceased cadaver. One significant advantage of using cadaver bone is that the surgeon can harvest any piece of or all of a bone, since there are no concerns of maintaining the structural or functional integrity of the donor bone. Furthermore, while cadaver bone is readily available and relatively easy and inexpensive to acquire, acquiring the precise size, shape, and density of such allograft material from a bone bank can often be extremely challenging.

There are further limitations associated with such allografts. Although proper handling can mitigate concerns, one important limitation is the possibility of disease transmission from the cadaver to the allograft patient. In addition to infectious disease, the recipient body may reject the foreign or allograft tissue, which can lead to further complications. Furthermore, the size, density, and other physical features of a bone can vary considerably from person to person, and depend upon the donor age, health, and other factors.

Since the graft implant site of the patient is usually not prepared and defined until the procedure is underway, the surgeon must compensate or adjust for the variability of available

bone autograft or allograft materials during the surgical procedure. At that time, it may also be difficult for the surgeon to obtain a piece of bone that is exactly the right size and shape or that has the proper load bearing capacities. Accordingly, the available bone graft material must be further modified before being implanted into the patient. The load bearing capacity of the available bone graft material is especially relevant to grafts to be effected in, for example, the bones of the leg or the spinal column. While cortical bone grafts will impart the needed strength to spinal or other high load bearing grafts, cancellous bone is more likely to encourage deposition of new bone so as to improve the likelihood of a successful graft and rapid recovery. Those skilled in the art have often amplified concerns that it is time consuming, difficult, and often impossible during the procedure to obtain an autograft or allograft bone piece of the most desirable size and with the most desirable ratio of cortical and cancellous bone that will optimize the strength and regeneration capabilities of the bone graft.

In addition to the iso- or autograft and allograft, another general type of graft is the xenograft. The xenograft is substantially similar to the allograft, except that the donor is of a different species than the recipient. The xenograft offers the advantage of a potentially plentiful supply of relatively inexpensive tissue. However, the xenograft shares many limitations with the allograft such as the risk of disease transmission and immune system rejection. In addition to the limitations that the xenograft shares with the allograft, the xenograft is only possible with those tissues that are compatible across different species. There are also ethical considerations involved when using or contemplating animal tissue as a substitute for human tissue. Because of these serious limitations, surgeons typically perform xenografts only in very limited situations.

Such bone grafts can be employed alone or in combination with other non-biological materials, instruments, and devices. Such non-biological grafts can incorporate or can replace auto- and allografts and can include, for example, artificial or synthetic materials and devices. In theory, non-biological materials, instruments, and device can avoid the limitations of disease transmission, immune rejection, and limited supply or availability of autografts and allografts. For example, surgeons sometimes use an artificial skin that is grown in a laboratory from one or a plurality of cell types, in place of skin auto- or allografts.

This technology has limited applicability, however, because the implanted material needs to perform many or most of the same structural and physiological functions as the tissue that is replaced. Furthermore, the material must be both biocompatible and stable under physiological conditions that can be extremely harsh. These limitations also apply to artificial bone grafts, instruments, and devices. As discussed above, bone tissue is not only a mechanical structure but is also a complex and diverse combination of living, dynamic, and continuously regenerating

tissues. Science can provide materials that mimic the structural properties of bone, but it has yet to discover a material that also duplicates its extraordinary biological properties and capabilities. Artificial bone materials do not always or in every patient readily encourage or support the deposition of new, living bone and are therefore not the always the preferred materials for bone grafts in every patient or in every malady.

With the preceding considerations in mind, those having knowledge in the art may comprehend that there are many considerations relevant to a determination of the most appropriate graft material and technique. If the patient and doctor elect an autograft approach, a suitable piece of bone must be excised from the patient before or during the graft procedure. On the other hand, if an allograft is preferred, a suitable donor bone piece, usually from a cadaver, must be ordered from a bone bank before the procedure is commenced. Regardless of which type of graft is elected, or even if both are needed, it may also be necessary to employ one or more artificial materials, instruments, and or devices to augment the graft procedure.

Even with the best and most thorough of pre-operative diagnoses and analyses, the surgeon typically can only define all of the size, shape, and strength parameters of the desired graft, whether it be allograft or autograft bone material, or artificial materials or components, or some combination thereof, once the damaged or injured tissues are visually inspected and resected and prepared for the graft during the procedure. If an autograft bone graft is to be used from the patient, the autograft materials is usually prepared at the same time by excising material from a donor bone such as a portion of the iliac crest or from the bone tissue being removed from the location of damage or injury. If an allograft bone piece is to be employed in the procedure, it must usually be modified before implant so that it can be properly sized and dimensioned to fit the space established for the graft after the original tissues are removed. Moreover, even if a detailed pre-procedure analysis establishes suitability for various artificial articles, such items are often modified during the procedure to accommodate specific anatomical variations only evident upon visual inspection and after preparation of the graft location.

Several attempts have been made to offer improved methods and devices that address some aspects of past problems and difficulties. For example, O'Leary et al. in U.S. Patent No. 5,073,373 and 5,484,601 are restricted to teaching, among other limitations, a bone powder that is includes cortical and or cancellous bone constituents that are reconstituted into implantable pastes and cakes. The O'Leary et al. bone powder may be suspended in glycerol, polyhydroxy compounds, or the like prior to being implanted. The O'Leary et al. approach has been attempted in many variations and also by others and all such attempts demonstrate several shortcomings that include the need for potentially immunogenic and inflammatory materials like animal

collagen and glycerol, which can have adverse consequences. Even without the possible consequences, the contemplated materials and compositions offer little to no immediate structural support that can alleviate symptoms such as stenosis and other sources of never root compression indicated in various spinal column anomalies.

Other examples in the prior art that are restricted to mechanical, bone powder-retaining devices such as a cage are described in U.S. Patent No. 5,489,308 to Kuslich et al. and 5,514,180 to Heggeness et al. The approaches advocated by Kuslich et al. and Heggeness et al. fail to, among other problems, establish an effective means to ensure that the graft instrument fuses into the host bone. Even though various elements are included that purport to facilitate such fusion, the suggested '308 and '180 instruments have only limited application since they cannot be modified to accommodate newly visualized in vivo size and shape parameters during a procedure without remachining of the contemplated material of the implant at the time of the implant, which defeats the preconfigured nature of the devices. Moreover, the '308 and '108 implant devices also will likely be subject to long-term displacement as the surrounding host bone tissue undergoes continual regeneration, which process can change the dimensions and profiles of surrounding host surfaces that can destabilize and loosen the implant thus necessitating another surgical procedure. U.S. Patent No. 5,910,315 to Stevenson et al. is similarly limited to combinations of the preceding devices wherein a metal cage is received into a bore in the host bone and is injected with a powered bone material. Here again the metal cage can be unseated and destabilized over time as the host tissues regenerate and the metal cage is not easily modified during the procedure to accommodate newly prepared and or visualized implant site size, shape, and load bearing requirements and parameters.

Still another approach is to use machined, prefabricated graft compositions that, in whole or in part, are bone tissue. Such graft compositions may be ground, compressed cancellous bone, cortical bone, or combinations thereof. The graft compositions can be shaped and machined into various shapes and sizes that can potentially accommodate a variety of graft or implant sites and environments. An example of the prior art that teaches this type of approach is U.S. Patent No. 6,371,988 to Pafford et al., which is limited to a graft material that is treated with compounds or proteins that can enhance the capability to act as a template for the deposition of new bone. Although this approach may address some of the limitations of the prior art, the surgeon has to choose correctly the size and shape of the graft before surgery. Another significant limitation of the '988 approach is that the surgeon is burdened with the need take time to precisely shape and mold the prefabricated '988 graft during the procedure. These types of modifications likely can eliminate many of the purportedly useful features of the Pafford et al. device before being

implanted. Moreover, the various limitations that Pafford et al. require can significantly increase the difficultly in obtaining suitably configured graft devices prior to the procedure, can increase the cost thereof, and will reduce the available supply of such bone graft material because of the tremendous loss of material incurred to fabricate the intricate features of the '988 device.

In attempts to avoid complications resulting form the use of ground bone as a graft material, artificial or synthetic bone grafts have been described in the art such as those in U.S. Patent Nos. 5,258,043 to Stone, 4,904,260 to Ray et al., and 5,626,861 to Laurencin et al. Each of these attempts is restricted to, among other elements, the use of prosthetic implant material, in various embodiments that are purportedly aimed at instigating improved rehabilitation of host vertebral bone and disc tissues. While the contemplated artificial or synthetic materials can be more easily supplied than other bone graft materials, the noted synthetics suffer from the pitfalls that they do not function in vivo in the same way that actual bone or bone-derived tissue functions with respect to structural integrity, load bearing capacity, fostering new bone deposition, and the like.

Yet another attempt to overcome the limitations of the prior art are illustrated in U.S. Patent Publication No. US 2002/0029084 to Paul et al. The teachings of Paul et al. are limited in many respects to the various methods and devices already discussed and contemplated hereinabove and fail in all respects to address all of the most troublesome difficulties the plague the art. The Paul et al. devices are restricted to, among other limitations, hybrid cortical and cancellous grafts having fixed predetermined shapes, sizes, and dimensions that are not readily reconfigurable during a procedure to easily accommodate the newly visualized, prepared, and possibly unusually configured implant site in a way that overcomes in any way the many shortcomings of the many prior art devices and methods.

What has long been needed but heretofore unavailable is a readily obtainable, relatively inexpensive, easily reconfigured, structurally useful, and rapidly assimilable bone graft device and bone graft kit that is suitable for use as an implant in a variety of bone graft procedures. The preferred method or device must reduce the burden on the surgeon during a selected procedure while maximizing the options available for preparing and presenting a bone graft implant that incorporates the most desirable shape, size, and dimensions for a given implant site. While being consonant with established medical practice, and while having wide compatibility with conventional surgical procedures, the desired bone graft should be especially well-suited for the most complicated procedures including, for purposes of example without limitation, corpectomies, discectomies, and other similarly complex reconstructive and rehabilitative procedures.

SUMMARY OF INVENTION

In its most general configuration, the present invention advances the state of the art with a variety of new capabilities and benefits while overcoming many of the shortcomings of prior devices in inventive and novel ways. In one of the many preferable configurations, a medical practitioner selects an appropriate number of cancellous bone pieces based upon the desired size of the graft. The practitioner, after removing damaged bone and tissue and preparing an implant site then assembles the bone graft device using one or more specially configured cortical bone pieces and surgically implants the graft to help to repair damage to bone caused by trauma, disease, or the like.

In one of many variations of the instant invention, the bone graft device is to be received in a prepared graft implant site in a patient. Such an implant site can be in any of a number of bone graft site locations such as, for purposes of example but not for limitation, an anteriorly approached spinal resection of one or more cervical, thoracic (or dorsal), or lumbar vertebrae of a spinal column of the patient. The bone graft implant site can be defined as a resection formed in any damaged or injured bone tissue, which can be, for further example, the spinal column resection that is most commonly referred to by those skilled in the relevant arts as a corpectomy wherein one or more vertebral body portions and intermediate vertebral discs are partially removed so that an inferior vertebral surface confronts a superior vertebral surface to establish the implant site.

The bone graft device preferably incorporates a plurality of pseudo-vertebrae that are each adapted with at least one transverse cross-sectional profile that is sized to be compatible for receipt and implant in the anterior spinal resection. The pseudo vertebrae can be wedge-shaped about a sagittal and or coronal cross-section and are preferably configured to be stacked end-to-end on one or more struts or stanchions, which can be positioned in a generally central aperture or in a multiple stanchion spaced apart configuration. At least one of the plurality of pseudo-vertebrae is formed with an exteriorly facing sill that frictionally confronts and is received against at least one of the inferior and superior vertebral surfaces. As best as possible, the sill surface is adapted to maximize frictional contact with the at least one of the vertebral surfaces. To avoid invading the vertebral channel or foramen of the spinal column, each pseudo-vertebral sill is sized and shaped to be, when introduced into and received in the resection, equal to or smaller than the transverse or horizontal cross-section of the vertebral bodies, which bodies define the superior and inferior vertebral body surfaces.

Additional modifications of the preferred embodiments may optionally or preferably incorporate at least one of the plurality of the pseudo-vertebrae to have a generally elongated cardioid cross-sectional horizontal or transverse profile. The cardioid profile can be proximal to the exteriorly facing sill such that the profile is approximately smaller than and for the most part is substantially circumscribed by the confronting proximate vertebral surface that is received against the sill.

A further variation of any of the preceding embodiments may also include the bone graft device being modified wherein at least one of the plurality of pseudo-vertebrae is formed to have a substantially wedge shaped cross section about a sagittal or coronal plane. In this configuration, the bone graft device can incorporate the exteriorly or outwardly facing sill to be more closely coplanar with and contacting the confronting vertebral surface, which vertebral surface can be, after the implant site has been prepared, somewhat oblique relative to a generally horizontal or transverse plane or section cut plane.

Any of the preceding configurations and embodiments may also be adapted to include any one of a number of the at least one pseudo-vertebra that can optionally or preferably be adapted to rotate, as the bone graft device is implanted into and introduced into the resection. The at least one pseudo vertebra can rotate about an axis that is substantially parallel with an axis of the at least one stanchion, and which stanchion and rotation axis can be substantially or approximately parallel with a substantially superior to inferior longitudinal hypothetical line that defines an intersection of a sagittal and a coronal plane. In this modified embodiment, a superior abacus pseudo-vertebra can rotate relative to a sandwiched drum pseudo-vertebra and an inferiorly stacked plinth pseudo-vertebra can similarly rotate relative to the drum. With this rotational capability, the superior abacus and the inferior plinth pseudo-vertebrae can, if also somewhat wedge-shaped, realign their respective exteriorly or outwardly facing sill surfaces to more closely be nearly or substantially coplanar with the confronting vertebral body surfaces against which the sill surfaces are received as the implant is introduced into the implant site.

While rotation of the superior-most (abacus) and inferior-most (plinth) pseudo-vertebrae may be optionally preferable, the one or more drum or intermediate pseudo-vertebrae can incorporate one or more key elements that are configured to prevent relative rotation between the one or more drum pseudo-vertebrae during and after implantation. Instead of or in combination with such key elements, the bone graft device may also be further optionally or preferably modified wherein one or more of the key elements cooperate with at least one strut or stanchion key, keyway, or corresponding key element that may be formed in the at least one stanchion. The

at least one stanchion key, keyway, or corresponding key element may be modified to prevent relative rotation between the at least one stanchion and the one or more drum pseudo-vertebrae.

The preceding embodiments and configurations may also be further configured to incorporate the one or more struts or stanchions that may be partially curved about an axis passing longitudinally therethrough from a superior end to an inferior end such that the lordotic or kyphodic curves of the spinal column can be more closely approximated with the assembled bone graft device. In yet additional modifications to any of the preceding arrangements, the bone graft device may incorporate the plurality of pseudo-vertebrae to be received about at least two stanchions whereby the pseudo-vertebrae are thereby keyed to prevent relative rotation between the pseudo-vertebrae. Each of the one or more struts or stanchions may be centrally or peripherally arranged when received with the pseudo-vertebrae to accommodate any of a number of possibly desirable structural configurations.

Any and or each of the preceding configurations and embodiments may also be adapted wherein the various bone graft device components, elements, and features are included in a kit that incorporates of plurality of variously configured, sized, shaped, dimensioned, and modified pseudo-vertebrae, struts or stanchions, and similar components that can be alternatively formed from isograft, allograft, and autograft bone pieces including cortical, cancellous, hybrid, as well as artificial materials, and combinations thereof.

These variations, modifications, and alterations of the various preferred embodiments may be used either alone or in combination with one another as can be better understood by those with skill in the art with reference to the following detailed description of the preferred embodiments and the accompanying figures and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Without limiting the scope of the present invention as claimed below and referring now to the drawings and figures, wherein like reference numerals, and like numerals with primes, across the several drawings, figures, and views refer to identical, corresponding, or equivalent elements, components, features, and parts:

FIG. 1 is an elevated perspective anterior view illustrating a bone graft device according to the principles of the instant invention in a pre-inserted and a seated position in vivo in a resection implant site of a cervical spinal column of a patient;

FIG. 2. is an elevated perspective oblique lateral or sagittal view, rotated and in reduced scale, of the bone graft device of FIG. 1, and with a portion of a thoracic or dorsal spinal column of a patient set apart for purposes of illustration;

FIG. 3 is a sinistral sagittal cross-sectional view, rotated and in modified scale, of a variation of the bone graft device of FIGS. 1 and 2;

FIG. 4 is a sinistral sagittal cross-sectional view, rotated and in modified scale, of another variation of the bone graft device of FIGS. 1, 2, and 3;

FIG. 5 is an elevated perspective view, in modified scale, of a pseudo-vertebra of the bone graft device of FIGS. 1 through 4 according to the principles of the instant invention;

FIG. 6 is an elevated perspective view, in modified scale, of a stanchion or strut of the bone graft device of FIGS. 1 through 4;

FIG. 7 is an elevated perspective assembly view, in modified scale, of the bone graft device of FIGS. 1 through 4;

FIG. 8 is an elevated perspective assembly view, in modified scale and with a portion of the device cut away for purposes of illustration, of the bone graft device of FIG. 7;

FIG. 9 is an elevated perspective view, in modified scale, of the stanchion or strut of FIG. 6;

FIG. 10 is a cross-sectional view, in modified scale, rotated and taken about section line 10-10 of FIG. 9;

FIGS. 11 through 13 are cross-sectional views, in similar scale, rotated and which could have been taken about a section line similar to that of section line 10-10 of FIG. 9 of variations of the stanchion or strut of FIGS. 6 and 9;

FIG. 14 is an elevated perspective view, in similar scale, of a variation of the stanchion or strut of FIGS. 6 and 9;

FIG. 15 is an elevated perspective view, in a similarly depicted scale, of the pseudo-vertebra of FIG. 5;

FIGS. 16 through 20 are elevated perspective views, in similar scale and rotated, of variations of the pseudo-vertebrae of the FIGS. 5 and 15;

FIG. 21 is an elevated perspective view, in similar scale, of a variation of the pseudo-vertebra of FIG. 17;

FIG. 22 is a superior transverse or horizontal view, in similar scale and rotated, of the pseudo-vertebrae of FIGS. 5 and 15;

FIG. 23 is a cross-sectional view, rotated, in similar scale, and taken about section line 23-23 of FIG. 22;

FIG. 24 is a cross-sectional assembly coronal or sagittal view, in similar scale, of multiple and stacked pseudo vertebrae of FIGS. 21 through 23;

FIG. 25 is an elevated superior perspective view, in similar scale, of a variation of the pseudo-vertebra of FIG. 20;

FIG. 26 is an elevated inferior perspective view, in similar scale, of the pseudo-vertebra of FIG. 25;

FIG. 27 is a superior transverse or horizontal view, in similar scale and rotated, of the pseudo-vertebrae of FIGS. 20, 25, and 26;

FIG. 28 is a cross-sectional view, rotated, in similar scale, and taken about section line 28-28 of FIG. 27;

FIG. 29 is a cross-sectional assembly anterior coronal view, in similar scale, of multiple and stacked pseudo vertebrae of FIGS. 25 through 28;

FIG. 30 is an elevated perspective superior view, in similar scale, of a variation of the pseudo-vertebrae of FIGS. 17, 21, and 25;

FIG. 31 is an elevated perspective superior view, in similar scale, of a variation of the pseudo-vertebrae of FIGS. 5, 15, 22, 23, and 24;

FIG. 32 is a cross-sectional view, rotated, in similar scale, and taken about section line 32-32 of FIG. 31;

FIG. 33 is a cross-sectional assembly sagittal or coronal or oblique view, in similar scale, of multiple and stacked pseudo vertebrae of FIGS. 31 and 32;

FIG. 34 is a cross-sectional assembly sagittal or coronal or oblique view, in similar scale, of multiple and stacked pseudo vertebrae of FIGS. 5, 15, 22, 23, 31 and 32;

FIG. 35 is an elevated perspective view, rotated and in similar scale, of a variation of the bone graft device assemblies of FIGS. 3, 4, 8, and 34;

FIG. 36 is an elevated perspective view, in reduced scale, of a variation of the bone graft device assembly of FIG. 35; and

FIG. 37 is an elevated perspective view, in reduced scale, of a variation of the bone graft device assembly of FIGS. 35 and 36.

Also, in the various figures and drawings, various reference symbols and letters are used to identify significant features, dimensions, objects, and arrangements of elements described herein below in connection with the several figures and illustrations.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In pushing the state of the art into heretofore uncharted territory, the bone graft device according to the principles of the instant invention establishes many new possible graft configurations and capabilities that are entirely absent from the many prior art attempts at improvements. The medical practitioner that employs any of the many contemplated embodiments, modifications, and variations of the bone graft devices of the instant invention can now more than ever focus on the complex and high-precision tasks before him or her without the need to expend substantial resources and valuable time on preparing, modifying, and attempting to overcome the deficiencies of prior bone graft devices. What is possible with the device according to the principles of the instant invention is a bone graft device that is more readily capable of rapid assimilation into and fusing with the host bone tissues, and which is also capable of rendering immediate and permanent structural support upon implantation. Each of these benefits can thus speed recovery and minimize the pain and discomfort otherwise likely to be experienced in various bone graft procedures.

With reference now to the various figures and especially FIGS. 1, 2, 3, and 4, those having knowledge in the relevant arts may understand that the preferred bone graft device **100** according to the principles of the present inventive technology incorporates an assembly of innovative components and elements. In practice, the instant invention is contemplated and susceptible for use in a number of possible procedures and implant sites that can include cervical, thoracic, and lumbar spinal column locations. More particularly and for purposes of example without limitation, the bone graft device **100** is depicted in FIG. 1as being assembled to be compatible for implant into a corpectomy-established anteriorly approached implant site **I** that is prepared and resected to span three cervical vertebral discs **D** and two vertebral bodies **C4**, **C5** of a cervical spinal column **S**, whereby the implant site **I** is defined or bounded to have a caudal or an inferior vertebral surface **IVS** confronting a superior or rostral or cranial vertebral surface **SVS**. The vertebral surfaces **IVS** and **SVS** are often also referred to by those skilled in the various arts, among other surgically colloquial nomenclatures, as end plates. The surfaces **IVS** and **SVS** can be prepared to be substantially parallel or non-parallel and or to be generally concave and or convex whereby only the least amount of damaged or injured tissue is removed so as to prepare the implant site **I** to have the maximum amount of remaining live bone tissue. For purposes of example without limitation, the proposed exemplary corpectomy procedure can achieve arthrodesis or fusion of the bone implant graft device **100** into the host tissue of the spinal column **S** as healing and recovery advance in the normal course to accomplish

decompression of the cervical column and the various nerve roots and enervated structures so as to reduce pain and discomfort that may be experienced by the patient from stenotic conditions or other anomalies.

The bone graft device **100** of FIG. 1 (for an example and illustrative cervical spinal procedure) and FIG. 2 (for an illustrative thoracic or dorsal spinal procedure) includes a generally stacked arrangement of pseudo-vertebrae **110** that can be adhesively joined or bound together or be otherwise stacked. The contemplated pseudo-vertebrae arrangement **110** can include, among other elements and features, a generally cranially or rostrally or superiorly positioned abacus pseudo-vertebra **120** and a generally caudally or inferiorly positioned plinth pseudo-vertebra **130** that together cooperate to sandwich one or more drum pseudo-vertebrae **140** when the pseudo-vertebrae **120, 130, 140** are received on a strut or stanchion **150**. The strut or stanchion **150** can be adapted to improve structural strength, rigidity, and alignment of the stacked pseudo-vertebrae **120, 130, 140**, among other possible features and capabilities. The strut or stanchion **150** extends generally superiorly to inferiorly or rostrally to caudally through or about the pseudo-vertebrae **120, 130, 140** and about an axis denoted generally by reference letter **A**. The abacus and plinth pseudo-vertebrae **120, 130** incorporate at least one exteriorly or outwardly facing respective sills **125, 135** that confront and are respectively received against the corresponding vertebral surfaces **SVS, IVS** (and in FIG. 2, **SVS', IVS'**).

For purposes of further illustration, an additional brace or stabilization instrument **B** that has been constructed and implanted is depicted with phantom lines in FIGS. 2, 3, and 4 as having been installed to the anterior or ventral portion of the various vertebral bodies (which could be installed in FIG. 1 on vertebrae **C3** and **C6** and which is shown in FIGS. 2, 3, and 4 installed on, for example without limitation, **T4** and **T7**) for added support. For improved illustration purposes, in FIG. 2 the exemplary **T5** and **T6** have been extended away along the depicted dashed extension lines from their respective actual positions in the thoracic or dorsal spinal column as reflected in FIGS. 3 and 4. In the configurations of the bone graft device **100** of FIGS. 1 and 2, the exteriorly or outwardly facing respective sills **125, 135** and the respectively corresponding and confronting vertebral surfaces **SVS, SVS'** and **IVS, IVS'** are adapted to be substantially parallel across the respective implant sites **I, I'**. However, as further described hereinbelow, the instant invention is also well-suited for purposes of and in applications where the respective sills **125, 135** and the respectively corresponding and confronting vertebral surfaces **SVS, SVS'** and **IVS, IVS'** are askew and substantially non-parallel.

In FIG. 3, which also depicts the noted exemplary thoracic or dorsal spinal corpectomy resection and graft implant procedure, an alternative bone graft device **160** is shown installed in

the implant site **I'** of the spinal column **S'**. The bone graft device **160** is similarly constructed to have a rostral or an abacus pseudo-vertebra **170** having a sill **175** received against superior or rostral vertebral surface **SVS'** and a caudal or a plinth pseudo-vertebra **180** with a sill **185** received against inferior or caudal vertebral surface **IVS'**. The vertebral surfaces **SVS'** and **IVS'** are depicted having been adapted to be substantially parallel, and the corresponding outwardly or exteriorly facing sills **175, 185** are generally similarly configured.

The abacus and plinth pseudo-vertebrae **170, 180** cooperate to sandwich a plurality of drum pseudo-vertebrae **190** in a stacked arrangement that is received upon strut or stanchion **195**. A different number of pseudo-vertebrae **170, 180, 190** are incorporated in this graft device **160** so as to accommodate compatibility with the differently dimensioned implant site **I'**. The various figures illustrate schematically proportioned pseudo-vertebrae, such as pseudo-vertebrae **120, 130, 140, 170, 180, 190**, to have similar shapes, profiles, and dimensions. However, the instant invention contemplates that such pseudo-vertebrae will have a variety of different shapes, dimensions, thicknesses, and cross-sectional profiles.

Such multiply configured pseudo-vertebrae can then be selected by the medical practitioner, once the implant sites, such as sites **I, I'**, have been prepared, so that an optimum fitting bone graft device **100, 160** can be arranged for a net or interference fit into the implant site **I, I'** to optimize structural support of the implanted bone graft device **100, 160**. For example, those skilled in the related arts should be able to comprehend that the pseudo-vertebrae **170, 180, 190**, can each have varied superior to inferior thicknesses so that the bone graft device **160** can be "shimmed" or otherwise sized about its gross top to bottom or superior to inferior dimension between sills **175** and **185** to fit into the implant site **I'** with a net fit or interference fit whereby the implant will be snugly and or tightly received into the implant site **I'**.

In FIG. 4, another implant site **I"** of a spinal column **S"** is illustrated and defined between non-parallel vertebral surfaces **SVS"** and **IVS"**. A bone graft device **200** is configured with generally wedge and or trapezoidally-shaped abacus and plinth pseudo-vertebrae **210, 220** that have respective inclined exteriorly facing sills **215, 225** that are adapted to be received against the non-parallel vertebral surfaces **SVS"** and **IVS"** to maximize contact there between. The medical practitioner in this instance has selected abacus and plinth pseudo-vertebrae **210, 220** to have suitably thick and cross-sectionally (about a sagittal or coronal cutting plane) shaped and dimensioned profiles so the contact interface between the exteriorly facing sills **215, 225** and the non-parallel vertebral surfaces **SVS"** and **IVS"** is maximized. In this way, the load path through the spinal column **S"** and the bone graft implant device **200** is optimized to offer the most possible post-operative or post-implant structural support. The abacus and plinth pseudo-

vertebrae **210, 220** sandwich drum pseudo-vertebrae **230** and all pseudo vertebrae **210, 200, 230** are received about at least one strut or stanchion **240**. The strut or stanchion **245** can be further optionally or preferably formed with generally non-parallel inclined ends **242, 245** for further improved interfacing with the vertebral surfaces **SVS", IVS"**.

With continued reference to the various figures and specifically now also to FIGS. 5, 6, 7, an 8, further details of the devices and components of the instant invention can be understood. A pseudo-vertebra **250**, which is schematically similar in construction in some aspects to the pseudo-vertebrae of bone graft devices **100, 160, 200**, is depicted and has a generally centrally or medially positioned aperture **255**. The aperture **255** can be positioned as shown or in any of a number of other equally suitable optional or preferable configurations that can better accommodate compatibility for use in a variety of implant site arrangements. The proposed aperture **255** can be incorporated for purposes of establishing a partial or through channel that can support and promote vascularization and or deposition of new bone tissue as fusion progresses. The aperture **255** can also serve as a recess for receiving a strut or stanchion or other stacking or alignment or keying elements. Additionally, the aperture **255** can be employed for both such capabilities and can be treated to have a surface roughness or smoothness or both along different portions, to have an elongated or through keyway or slot for alignment, and or to have a coating that can promote more rapid bone deposition and or ossification.

The pseudo-vertebra **250** can be generally cylindrically shaped and can also have any of a number of other possible shapes, thicknesses, wedged cross-sections, and the like as further disclosed elsewhere herein. Moreover, although shown as a substantially single material construction, the pseudo-vertebra **250** can be formed from one or more cancellous or cortical auto-, iso-, or allograft bone tissues, and or can be formed from any of a wide range of artificial materials that can include glass, ceramic, metal, composite, fiber, polymer, and other biocompatible materials, and alloys, hybrids, and combinations and compositions thereof. Among many other possible combinations, a particularly capable arrangement of the variously configured pseudo-vertebrae described herein, including for purposes of illustration but not for purposes of limitation pseudo-vertebrae **250**, can be preferably or optionally adapted to be formed from a densified, compressed, or otherwise treated cancellous bone material to have improved load bearing, structural, fusion, and related properties, capabilities, and characteristics.

Additionally, wherein the various strut or stanchion configurations illustrated herein can be formed from any of a variety of the materials described in connection therewith and from any of the materials described in connection with the pseudo-vertebrae, for purposes of example only and not for purposes of limitation the contemplated struts and stanchions, such as struts and

stanchions **150**, can be formed from a cortical bone or other structurally similar and capable material that can be treated in any number of ways so as to improve its structural and fusion or arthrodesis capabilities and characteristics. Another suitable capable material that is useful for construction of the contemplated struts and stanchions can be formed from any number of possible polymerics and carbon fiber composites and alloys, hybrids, and compositions thereof, which materials can be adapted to closely match the structural properties of the native skeletal bones and structures or to be especially compatible for use in bone graft devices that are to be employed in the noted load sharing configurations.

In the contemplated construction of bone graft device **100** wherein the optional or preferred pseudo-vertebrae are formed from a substantially compressed cancellous bone material and the optional or preferred struts or stanchions are formed from a stronger material such as a cortical bone or a compatible non-biological material, especially efficacious load sharing can result in certain configurations after the device **100** has been implanted whereby the fusion process can be accelerated under certain circumstances. As may be known to those skilled in the various related arts, during the post-implant fusion process, the deposition of new bone tissue can at a biological molecular level be a direct function of the structurally induced stress loading upon the implanted and native structures in a given bone graft implant site. Accordingly, in circumstances where the implanted bone graft or other device bears little to no stress loading, a probability can exist wherein fusion and integration of the implanted graft and or device occurs very slowly if at all. This effect can be especially pronounced in applications wherein a brace or stabilization device, such as brace **B** (FIGS. 2, 3) is employed to bear the majority of the structural skeletal loads in combination with a bone graft implant such as bone graft device **100**. Attempts to ensure that the skeletal forces and loads are shared between such a brace or stabilizer and the implanted bone graft have included developments in brace technology wherein the practitioner can effect what has been referred to in the art as a dynamism parameter in the brace construct that allows some range of motion or degree of freedom in the braced native skeletal structures such as the native vertebrae so that the implanted bone graft, such as bone graft device **100** is subjected to loading in the ordinary course of movement of the body of the patient. In this way, the brace **B** shares a part of the stresses and loads with the implanted bone graft, which can under certain circumstances improve the fusion process of the implanted graft. Such load sharing concerns can also have an important role as to the various components of the contemplated bone graft device **100**.

More particularly, wherein the device **100** is selected to have a combination of cortical and cancellous materials, the good fusion results have been experienced in various procedures

where the overall structural properties of the implanted bone graft device are identical to or similar to that of the native skeletal structures. Even more specifically, for purposes of example without limitation, among other useful properties and considerations, good fusion results have been obtained with bone graft devices that have been adapted such that the resultant structural modulus of elasticity and the flexure of the proposed bone graft devices is identical to or substantially or approximately the same as that of the native bone and skeletal structures that are being repaired, reconstructed, rehabilitated, and otherwise modified as part of the graft procedure. Additionally, in hybrid applications where a combination of cancellous and or cortical bone materials are used in combination with non-biological materials, including for example without limitation, polymerics and carbon fiber materials, good results are similarly obtained when load sharing is implemented and the hybrid and or composite bone graft device is adapted to have identical or substantially or approximately similar structural properties, characteristics, and capabilities, such as identical or approximately or substantially similar flexure and or modulus of elasticity, among other possibly desirable similarities. In such additionally contemplated load sharing hybrid bone graft applications, any of the contemplated pseudo-vertebrae, struts, stanchions, and other components can be formed from the noted materials.

Additionally, pseudo-vertebra **250** as well as any of the other components of the proposed bone graft device **100** and the variations, modifications, and alternative configurations thereof, can incorporate an exterior coating about transverse surfaces **260**, **265** (which can be the vertebral surface interfacing sills described elsewhere herein) and or about exterior surface **270**. For embodiments formed from composite and hybrid compositions of such materials and or non-biological materials, the contemplated coatings and treatments can be incorporated into the substrates during formulation and or during fabrication into the components described herein. Such treatments and coatings can include a cancellous and or cortical bone chip, powdered, paste, liquid, or other material that can also include various other substances, such as growth factors and the like, which materials and substances can be adapted to further stimulate assimilation and fusion into the host implant site and with other components and elements of the contemplated bone graft devices. Additionally contemplated and potentially efficacious treatments and coatings can include, for purposes of further example but not for purposes of limitation, demineralization, antitumor and chemotherapeutic agents, antibiotics, bactericides, fungicides, and other similarly capable biocides, as well as a range of possibly suitable osteobiologics that can control, limit, protect, and or promote or augment the implant site environment and constituents therein as well as being able to control, limit, and or promote the

growth of tissues. Such coatings and treatments can be adapted for immediate and or time release into the implant site from the bone graft either through leeching or as the bone material of any such graft is absorbed and regenerated, and can be especially useful in various procedures and in certain patients not only for improving probabilities for successful fusion and arthrodesis, but can also and or concurrently be useful for limiting, controlling, and possibly eliminating infections, reinfections, and growth rates of regenerated tissues and the like.

In FIG. 6, a strut or stanchion **280** is illustrated that can be similar in construction in many respects to any of the other struts and or stanchions described elsewhere herein, including for example struts or stanchions **150, 195, 240**. The strut or stanchion **280** can further be defined by rostral or superior end **285** and a caudal or inferior end **290** and with an outer surface **295**. The strut or stanchion **280** can be fabricated with any type of curvature **282** from any of the aforementioned materials and can be treated and or coated in any manner similar to that already described in connection with the possible embodiments of the variously contemplated pseudo-vertebrae **250** illustrated herein above and below. Although a substantially elongated cylindrical profile is schematically represented in the depiction of strut or stanchion **280**, a variety of other equally suitable shapes and configurations is contemplated and should be understood with reference to the other figures and descriptions herein. The general views of FIGS. 7 and 8 depict various constructions of bone graft devices in different stages of assembly that are fabricated in general from the pseudo-vertebra **250** and the strut or stanchion **280** of FIGS. 5 and 6.

With continued reference to the various preceding illustrations and now also to FIGS. 9 through 13, further capabilities and features of the instant invention can be understood. In FIG. 9, the stanchion or strut **280** of FIG. 6 is shown for purposes of explicating additional details of contemplated constructions and parameters. Here again, although the demonstrative illustrations of FIG. 9 and the generally transverse cross-section of FIG. 10 reflect a generally cylindrical configuration, any of a number of other configurations are suitable, including the ellipsoid configuration **300** of FIG. 11, the ovoid configuration **305** of FIG. 12, and the triangular profile **310** of FIG. 13. The instant invention contemplates such struts and stanchions for use in wide range of possible bone graft implant sites and the various parameters, configurations, and arrangement of such sites will establish preferred dimensions and parameters of the most desirable strut and stanchion. In the exemplary and illustrative but non-limiting context of spinal column rehabilitative procedures, such as corpectomies, a range of suitable dimensions and parameters have been identified that can be particularly well-suited for purposes of the instant invention. While the struts and stanchions illustrated herein can be sized and shaped to substantially fill the corresponding apertures of the contemplated pseudo-vertebrae or other bone

graft element adapted for use with other non-spinal corporeal bone implant sites, such struts and or stanchions may also be substantially undersized so as to establish an interstice between the exterior surface of the strut or stanchion and the inside surface of the aperture, which surfaces of the proposed interstice can be treated, coated, or otherwise configured to promote interstitial vascularization and bone deposition.

More particularly, the stanchion or strut **280** for use in such procedures can have a range of optional or even preferable diameters "δ" (Greek letter delta) that can preferably be in the range of about 2 to 10 millimeters, and more preferably between about 2 and 7 millimeters, and even more preferably between approximately 3 and 5 millimeters. A preferred or optional range of lengths "λ" (Greek letter lambda) will depend upon the mean average distance between the confronting vertebral surfaces, such as surfaces **SVS, IVS** and how large of a graft is to be implanted. In the context of spinal column procedures, the length of the strut or stanchion **280** will be a function of many levels of vertebral bodies and discs that are to be spanned by the bone graft device, and the relative conditions and dimensions of the vertebral bodies and discs that exist in the operative location to be addressed by the procedure. In the cervical region of the contemplated spinal column, and subject to further modification as a result of any pronounced stenotic or other degenerative and traumatic conditions that may be present, the mean average longitudinal span across a sagittal or coronal cutting plane per cervical level can range between about 20 and 25 millimeters per vertebral body and approximately between 2 and 5 millimeters per vertebral disc. In the continued context of spinal column graft procedures, the lumbar region can present per level spans that range about 40 millimeters per vertebral body and between about 2 and 12 millimeters per vertebral disc. The thoracic region presents vertebral body and disc longitudinal spans between those of the cervical and lumbar regions of the spinal column. With these considerations in mind, the contemplated strut or stanchions **150, 195, 240, 280** could therefore preferably have a two-cervical level dimension λ in the range of between about 46 and 65 millimeters, which depend not only on the indigenous structural geometry of the spinal column to be rehabilitated, but also upon the precise parameters of the implant site established as the injured tissues are resected prior to implanting the proposed bone graft device according to the principles of the instant invention.

With reference now also specifically to FIG. 14, various other possible preferable or optional alternative arrangements are suggested that can include a strut or stanchion **320** that is adapted to have a simple or compound curvature **325** that can have a simple radius "ρ" that can be selected to specifically accommodate any native curvature present at the proposed implant site, if any. In the context of the exemplary spinal column procedures, such curvature **325** and

radius ρ can be selected to approximate the particular nominal and abnormal lordotic and kyphodic, or even compound scoliotic, curvature of the spinal column at the region of the proposed implant site.

In FIGS. 15 through 21, various contemplated shapes, dimensions, and profiles of the proposed pseudo-vertebrae according to the principles of the instant invention are illustrated. With continued reference to the preceding figures and now also specifically to FIG. 15, the pseudo-vertebra **250** of FIG. 5 is represented again for comparison and further explication in the context of various other possible configurations.

The pseudo-vertebra **250** of FIG. 15 is formed to have a substantially rectilinear sagittal or coronal cross-section with an average generally uniform thickness **253** and to incorporate aperture **255** and one or more surface treatments about surfaces or sills **260, 265**, which surface treatments can be substantially smooth and or include, for purposes of example without limitation, surface roughening elements that cover a portion of or all of the surfaces **260, 265**. Such surface roughening features can include pointed and or diamond patterned dimples and stipples that are adapted to grip interfacing surfaces, such as the vertebral body surfaces **SVS, IVS** and the corresponding surfaces and or sills **260, 265** of adjacent stacked pseudo-vertebra **250** (see, e.g., FIGS. 2 - 4, 7, 8). Moreover, the surfaces and or sills **260, 265** can also further optionally or preferably incorporate or be coated with any of the contemplated coatings described herein elsewhere that can promote more rapid fusion and integration of the pseudo-vertebra into the host spinal column **S, S', S"**.

In FIG. 16, pseudo-vertebra **330** is shown being formed with a generally trapezoidal and or wedge shaped cross section and to define what is depicted as a generally medially positioned aperture **332**. The pseudo-vertebra **330** is formed with the noted wedge or trapezoidal shape to have a substantially average minimum superior to inferior thickness **333** and a substantially average maximum similar thickness **334**, and with sills **335, 337**. As with preceding embodiments, any of a variety of surface treatments and coatings may be similarly incorporated. Adapted with similar thickness, surface, and coating features, another modified embodiment is illustrated by pseudo-vertebra **340** that is adapted to have aperture **342**, sills **345, 347**, and an elongated or what may otherwise be referred to as a cardioid, lunular, semilunate, and or crescentric transverse or lateral cross-sectional profile, which is especially well-suited for compatibility with various of the similarly shaped vertebral bodies of the cervical, thoracic, and lumbar spinal columns.

In FIG. 18, a generally cylindrical pseudo-vertebra **350** incorporates through apertures **352** that are formed between surfaces or sills **355** and **357** and which can be cooperatively used

as what can be referred to as key-ways to key or align the stacking arrangement of multiple such pseudo-vertebrae **350**. Similarly, pseudo-vertebrae **360, 370** (FIGS. 19, 20) respectively incorporate through keyway apertures **362, 372** between respective superior surfaces **365, 375** and inferior surfaces **367, 377**. As with preceding embodiments, configurations, and modifications, each of such pseudo-vertebrae **350, 360, 370** are easily further adapted to include any of the noted surface treatments and coatings already described in connection with other such pseudo-vertebrae.

With continued reference to the preceding figures and now also specifically to FIGS. 21 through 29, the variously described pseudo-vertebrae embodiments and variations thereof are each all adapted to have various profiles as well as specific preferred and optional ranges of dimensions that are adapted to be specifically compatible for use in the respective implant sites wherein the specially configured and or assembled bone graft devices according to the principles of the instant invention are to be introduced. More specifically, and with reference now to FIG. 21, the pseudo-vertebra **340** is again depicted and is here labeled to have a thickness τ (the Greek letter tau) that can be selected to have a wide range of possible dimensions.

Typically, even though shown schematically in the various figures to have substantially similar thickness proportions, the actual preferred pseudo-vertebrae contemplated herein will be formed to have a wide range of such possible thicknesses τ that can be in the range of wafer-thin shimming configurations of about 10ths of a millimeter to sizes as large as longest span to be grafted in an adult human, which can include non-vertebral graft, rehabilitative, and reconstructive applications and procedures. In the exemplary context of spinal column grafts illustrated herein, the possible pseudo-vertebrae can be sized to span an implant site that is established across one or more levels of a large spinal lumbar vertebra and vertebral discs.

Such large nominal and healthy adult human lumbar vertebrae can be as thick about a substantially superior to inferior longitudinal or sagittal axis as between about 35 to 45 millimeters; and, such large nominal and healthy lumbar region vertebral discs can be as thick as 10 to 15 millimeters. As those skilled in the art can appreciate, such a pseudo-vertebrae thickness could thus range as high as the corresponding thickness of 2, 3, or more such lumbar levels and can be as tall as 60 to 120 millimeters or more. The thinner shimming configurations can be very well-suited for precisely configuring the proposed and contemplated bone graft devices of the instant invention.

In the generally cylindrical embodiments of the proposed and various inventive pseudo-vertebrae configurations, an average exterior generally lateral or transverse dimension is implemented to be compatible for use in the proposed graft implant site. In the context of the

exemplary spinal column application described herein, the contemplated pseudo-vertebrae should be constrained to have a profile that can maximize the surface area available for transfer of loads across the implant. At the same time, the exterior profile of the proposed pseudo-vertebrae should readily fit within the confines of the pre-prepared implant site. Additionally, the pseudo-vertebrae are optimized, in the previously illustrated cardioid, semi-lunate or lunular configurations to transfer loads across as much of the interfacing vertebral body as possible while avoiding invasion of the vertebral canal or channel that contains the spinal cord nerve roots.

With specific reference to FIG. 22, the previously described pseudo-vertebra **250** is depicted to have an average generally diametrical approximate maximum dimension δ (the Greek letter delta) that is adapted to be specifically compatible with a minimum corresponding diametrical lateral or transverse dimension of an implant site, such the interfacing inferior vertebral surfaces **IVS, IVS', IVS"** and the respectively confronting superior vertebral surfaces **SVS, SVS', SVS"**. While the maximum average diametrical dimension δ of the contemplated pseudo-vertebrae embodiments will depend upon whether a patient presents a nominally sized, healthy spinal columnar body at the pre-prepared implant site, such as exemplary vertebral body implant sites **I, I', I"**, a variety of possible dimensions can be implemented for compatibility with the proposed implant site.

To further illustrate the possible pseudo-vertebrae dimensions δ of the spinal column procedures that are contemplated for purposes of illustrating specific proposed applications, nominally health adult cervical vertebral bodies can have lateral or transverse cutting plane dimensions in the range of about 18 to 22 millimeters across a generally anterior to posterior (or ventral to dorsal) axis in the noted lateral or transverse plane, and approximately between 22 to 28 millimeters about a generally dextral to sinistral axis also in the lateral or transverse plane. In the lumbar spinal column, the corresponding approximate maximum dimensions for δ can be in the range of about 30 to 50 millimeters about the dorsal to ventral and sinistral to dextral axes spanning the transverse or lateral planes. A similar analysis and set of dimensional requirements can be discerned and applied to alternative configurations of the components that will replace the pseudo-vertebrae explicated in detail herein and which are adapted for compatibility with bone graft devices and procedures for any other part of the body that is to be addressed with any of a number of bone graft applications and procedures.

In the partially assembled schematic stacking diagrammatic representation depicted in FIG. 24 of an exemplary bone graft device, the pseudo-vertebrae, such as pseudo-vertebrae **250** are stacked in the direction generally indicated by the arrows labeled with reference letter σ (the lowercase Greek letter sigma). Any of the contemplated varied thicknesses of the contemplated

pseudo-vertebrae **250** are stacked together, perhaps on a strut and or stanchion and or with an adhesive or binding substance (not shown), to establish a bone graft device having length λ (the lowercase Greek letter lambda) that most closely matches or nearly matches the corresponding generally longitudinal length or distance of the shortest distance between the interfacing surfaces of the implant site, such as the interfacing inferior vertebral surfaces **IVS, IVS', IVS"** and the respectively confronting superior vertebral surfaces **SVS, SVS', SVS"** already described hereinabove.

In FIGS. 25, 26, 27, 28, and 29, yet another possible key and alignment feature and capability is contemplated for use with any of the preceding embodiments, components, variations, and modifications. A pseudo-vertebra **380** can have a similar shape and construction to any of the preceding such pseudo-vertebrae to have at least one aperture **382** for receipt onto a strut and or stanchion (not shown), and outwardly facing surfaces **385, 387**. The proposed enhanced pseudo-vertebra **380** may also incorporate one or more keying elements such as keying stipples **390** and corresponding keyway dimples **392**. If a generally cardioid or lunular profile is selected for pseudo-vertebra **380**, it can be adapted in a fashion so as to maximize the load bearing surface area of surfaces **385, 387** that is available for load transfer across the pseudo-vertebra **380**, while ensuring that when implanted at a spinal column implant site, the pseudo-vertebrae does not invade the spinal canal or channel, or foramen of the vertebra spanned by the assembled and implanted bone graft device. To illustrate yet another example of a specific approach to accomplish this objective, the pseudo-vertebra **380** may be formed with a transverse or lateral, sinistral to dextral dimension "l" (a lowercase Roman letter "L") (FIG. 27) and a transverse or lateral, ventral to dorsal dimension "**w**" (a lowercase Roman letter "W") (FIG. 27). In this way, a proposed alternative bone graft device **395** (FIG. 29) may be formed having multiply dimensioned thicknesses τ (FIG. 28) stacked in a direction σ to have a total bone graft device **395** stack height λ (FIG. 29) for implanting into an implant site such as that already described herein.

In any of the preceding embodiments, any of the proposed and contemplated bone graft devices may have one or more such pseudo-vertebrae that can have dissimilar profiles, thicknesses, and lateral dimensions so as to establish compatibility for any of a number of possibly unusual implant site configurations. More specifically, a substantially thin, wedge or trapezoidally and cylindrically profiled pseudo-vertebra can be selected as an abacus or superior-most element, while relative thicker lunular pseudo-vertebrae may be selected and incorporated as drum or intermediate pseudo-vertebrae, while a plinth or inferior-most pseudo-vertebra having yet another shape, profile, and thickness can be incorporated so as to form a complete bone graft

device that can be well-suited for a specific and peculiar implant site not otherwise expressly disclosed herein.

In yet other examples, in general, any of the precedingly described components and features can be incorporated in other manners so as to address other implant site and contemplated bone graft device peculiarities and objectives. More specifically, and with reference now also to FIGS. 30 to 33, another variation of a pseudo-vertebra **400** is depicted that includes an aperture **402 (422)** for stacking or other purposes, exteriorly facing surfaces or sills **405, 407**, and a substantially minimum thickness **410** and a generally maximum thickness **415**. The varied thicknesses **410, 415** are intended only to illustrate that a generally trapezoidal shape is implemented. However, the what may be referred to as a lofted surface that spans the surface between the minimum and maximum thickness can be planar or undulating and can establish any of a number of possible interfacing surfaces that can incorporate any of the previously described surface treatments, finishes, and coatings, as well as being adapted to interface with a specifically profiled superior or inferior graft interface surface at the implant site. More specifically, the surface or sills **405, 407** may be further shaped to also define a substantially concave or convex or other lofted surface profile that can establish automatic seating of the surfaces or sills **405, 407** against the interfacing implant site surfaces, such as inferior and superior vertebral surfaces **IVS, IVS', IVS", SVS, SVS', SVS"**. Varied thicknesses **430, 435** (FIG. 32) are noted to illustrate the possibly desirable wedge shape.

With specific reference to FIG. 33, such new and novel arrangements of pseudo-vertebrae, or the contemplated counterpart bone graft components adapted for use with other non-spinal corporeal graft implant sites, can be stacked to form a substantially curved bone graft device **440** that defines a curvature σ' (FIG. 33) that can be received about a strut or stanchion (not shown) having a generally corresponding curvature **445** and which can be similar in construction in certain aspects to stanchion or strut **320** of FIG. 14. In this way, the alternative bone graft device **440** can be established to more readily match or mimic the natural lordotic or kyphodic curvature on the exemplary spinal implant sites **I, I', I"** contemplated herein as well as any other curvature indigenous to another non-spinal corporeal bone implant site.

In yet another proposed alternately configured variation, a bone implant device **450** can incorporate one or more of the previously illustrated pseudo-vertebrae such as pseudo-vertebrae **420** being positioned as the abacus superior-most and plinth inferior-most pseudo-vertebrae and stacked in direction $\sigma"$ about an intermediate drum pseudo-vertebra such as pseudo-vertebra **250**. In this alternative arrangement, the exteriorly or outwardly facing surfaces **425, 427** can be established to present such surface being inclined relative to a otherwise non-inclined plane **455**

that is generally orthogonal to a coronal or sagittal plane **460**. This representative configuration can be readily sized for compatibility with confronting interfacing surfaces such as any of the possibly obliquely fashioned inferior and superior vertebral surfaces described elsewhere herein.

In FIG. 35, another possible bone graft device **470** is shown that can incorporate a modified drum pseudo-vertebra **475** that can be similar in some aspects to pseudo-vertebra **250** but that is modified, for non-adhesively joined graft stack arrangements wherein the intermediate pseudo-vertebrae confronting surfaces are substantially smooth, to be alignable with a keyway shaped aperture having a shape that can resist rotation, such as a substantially triangular shape, so as to ensure desired alignment of the pseudo-vertebrae remains undisturbed as the bone graft device **470** is introduced to the implant site. A strut or stanchion **480** can be also included that is received with the drum pseudo-vertebrae **475** and that is adapted with a rotation resistant cross-sectional profile that is compatible with the apertures of the pseudo-vertebrae. The strut or stanchion **480** can also further be formed with substantially cylindrical pins **482** at one or both ends that are joined or merged into corresponding pin seats **485**, through which pins **482** and seats **485** passes an axis of rotation **487**. Received about the pins **482** and seated against the seats **485** are additional wedge-shaped pseudo-vertebrae **490** that are adapted to rotate substantially in a plane of rotation denoted by reference arrows **495**. In this configuration, the alternatively proposed bone graft device **470** can be introduced into the graft implant site whereby the rotation capable pseudo-vertebrae **490** can rotate into a more closely interfacing alignment with the confronting pre-prepared surfaces of the implant site, which implant site surfaces can be non-parallel or somewhat oblique. This arrangement further establishes an even more closely aligned and more perfectly fitted implanted bone graft device **470**, which in turn improves load bearing paths across the rehabilitated structure and which can further accelerate the deposition of new bone and ensuing fusion of the implant into the host tissue.

In FIG. 36, a partially assembled bone graft embodiment representative of the instant invention is depicted in bone graft device **500**, which device **500** can include any of the previously described components, elements, and features. The device **500** incorporates the pseudo-vertebra **350** that are received on one or more stanchions or struts **280**, which pseudo vertebrae **350** are stacked together in an aligned relationship to establish the bone graft device **500** sized to be implanted at a selected graft implant site such as any of those noted herein elsewhere. In FIG. 37, another partially assembled bone graft device **550** according to the principles of the instant invention is illustrated and includes one or more pseudo-vertebrae **560** adapted with substantially peripherally positioned keyway apertures **565** that are adapted to receive compatibly configured struts or stanchions **570**. In this device **550**, substantially higher

load bearing capabilities can be established for possible use in very high load bone graft implant sites such as, for purposes of example without limitation, legs, arms, and lumbar spine regions of the body.

Numerous alterations, modifications, and variations of the preferred embodiments disclosed herein would be apparent to those skilled in the art and they are all contemplated to be within the spirit and scope of the instant invention, which is limited only by the following claims. For example, although specific embodiments have been described in detail, those with skill in the art can understand that the preceding embodiments and variations can be modified to incorporate various types of substitute and/or additional materials, relative arrangement of elements, and dimensional configurations for compatibility with the wide variety of possible bone graft devices and kits that are available in the marketplace. Accordingly, even though only few embodiments, alternatives, variations, and modifications of the present invention are described herein, it is to be understood that the practice of such additional modifications and variations and the equivalents thereof, are within the spirit and scope of the invention as defined in the following claims.

I CLAIM:

1. A bone graft device adapted to be received in an anterior spinal resection of one or more vertebrae of a spinal column, the resection being defined between an inferior vertebral surface confronting a superior vertebral surface, each surface being bounded by a respective periphery defining the extents of the respective area of the surface, comprising:

a plurality of pseudo-vertebrae adapted with a cross-sectional profile compatible for implant in the anterior spinal resection;

at least one stanchion receiving the plurality of pseudo-vertebrae in a generally stacked arrangement;

wherein at least one of the plurality of pseudo-vertebrae defines an exteriorly facing sill configured to be received against at least one of the inferior and superior vertebral surfaces to maximize contact between the surfaces; and

wherein each sill is sized and shaped to be substantially circumscribed by at least one of the respective vertebral surface peripheries when received there against so as to not invade the vertebral channel of the spinal column when the bone graft device is introduced into and received in the resection.

2. The bone graft device according to Claim 1, wherein at least one of the plurality of pseudo-vertebrae has a generally elongated cardioid cross-sectional profile proximal to the sill that is substantially circumscribed by the proximate vertebral surface.

3. The bone graft device according to Claim 2, wherein the proximal vertebral surface is formed in a cervical vertebral body.

4. The bone graft device according to Claim 2, wherein the proximal vertebral surface is formed in a thoracic vertebral body.

5. The bone graft device according to Claim 2, wherein the proximal vertebral surface is formed in a lumbar vertebral body.

6. The bone graft device according to Claim 1, wherein at least one of the plurality of pseudo-vertebrae is formed to have a substantially wedged shaped cross section about a sagittal plane.

7. The bone graft device according to Claim 6, wherein the at least one pseudo-vertebra is adapted to rotate, as the bone graft device is introduced into the resection, about an axis substantially parallel with an axis of the at least one stanchion.

8. The bone graft device according to Claim 1, wherein the at least one stanchion is at least partially curved about an axis passing longitudinally therethrough.

9. The bone graft device according to Claim 1, wherein the pseudo-vertebrae are received about at least two stanchions.

10. The bone graft device according to Claim 1, wherein the at least one stanchion is substantially medially disposed about the plurality of pseudo-vertebrae.

11. The bone graft device according to Claim 1, wherein the at least one stanchion is substantially peripherally disposed about the plurality of pseudo-vertebrae.

12. A bone graft device adapted to be received in an anterior spinal resection of one or more vertebrae of a spinal column, the resection being defined between an inferior vertebral surface obliquely confronting a superior vertebral surface, each surface being bounded by a respective periphery defining the extents of the respective area of the surface, comprising:

at least three pseudo-vertebrae each adapted with a cross-sectional profile compatible for implant in the anterior spinal resection and further including (1) abacus and plinth pseudo-vertebra each having a substantially wedged shaped sagittal cross section and respective exteriorly facing sills adapted to maximize contact with the respective superior and inferior vertebral surfaces, and (2) at least one drum pseudo-vertebra stacked between the abacus and plinth pseudo-vertebrae;

at least one stanchion receiving the plurality of pseudo-vertebrae in a generally stacked arrangement;

wherein at least one of the abacus and plinth pseudo-vertebrae are rotatably received about the at least one stanchion; and

wherein each sill is sized and shaped to be substantially circumscribed by at least one of the respective vertebral surface peripheries when received there against so as to not invade the vertebral channel of the spinal column when the bone graft device is received in the resection.

13. The bone graft device according to Claim 12, wherein at least one of the plurality of pseudo-vertebrae has a generally elongated cardioid cross-sectional profile proximal to the sill that is substantially circumscribed by the proximate vertebral surface.

14. The bone graft device according to Claim 13, wherein the proximal vertebral surface is formed in a cervical vertebral body.

15. The bone graft device according to Claim 13, wherein the proximal vertebral surface is formed in a thoracic vertebral body.

16. The bone graft device according to Claim 13, wherein the proximal vertebral surface is formed in a lumbar vertebral body.

17. The bone graft device according to Claim 12, wherein the at least one stanchion is at least partially curved about an axis passing longitudinally therethrough.

18. The bone graft device according to Claim 12, wherein the at least one stanchion is substantially medially disposed about the plurality of pseudo-vertebrae.

19. The bone graft device according to Claim 12, wherein the at least one stanchion is substantially peripherally disposed about the plurality of pseudo-vertebrae.

20. The bone graft device according to Claim 12, further including at least two drum pseudo-vertebra that are stacked between the abacus and plinth pseudo-vertebrae, and wherein the at least two drum pseudo-vertebrae incorporate at least one key element adapted to prevent relative rotation between the at least two drum pseudo-vertebrae.

21. The bone graft device according to Claim 20, wherein the respective at least one key elements cooperate with at least one stanchion key element formed in the at least one stanchion and adapted to prevent relative rotation between the at least one stanchion and the at least two drum pseudo-vertebrae.

22. The bone graft device according to Claim 20, wherein the at least one key element is formed in at least one of the drum pseudo-vertebrae and is adapted to engage another of the at least two drum pseudo-vertebrae to prevent relative rotation there between.

23. A bone graft kit adapted to assemble a bone graft device to be received in an anterior spinal resection of one or more vertebrae of a spinal column, the resection being defined between an inferior vertebral surface confronting a superior vertebral surface, each surface being bounded by a respective periphery defining the extents of the respective area of the surface, comprising:

a plurality of pseudo-vertebrae adapted with a cross-sectional profile compatible for implant in the anterior spinal resection wherein the pseudo-vertebrae of the plurality include at least one of shim, drum, and wedge pseudo-vertebrae;

at least one stanchion receiving the plurality of pseudo-vertebrae in a generally stacked arrangement, the at least one stanchion including at least one of a cylindrical, a keyed, and a curved stanchion;

wherein at least one of the plurality of pseudo-vertebrae defines an exteriorly facing sill configured to be received against at least one of the inferior and superior vertebral surfaces to maximize contact between the surfaces; and

wherein each sill is sized and shaped to be substantially circumscribed by at least one of the respective vertebral surface peripheries when received there against so as to not invade the vertebral channel of the spinal column when the bone graft device is received in the resection.

24. The bone graft device according to Claim 23, wherein at least one of the plurality of pseudo-vertebrae has a generally elongated cardioid cross-sectional profile proximal to the sill that is substantially circumscribed by the proximate vertebral surface.

25. The bone graft device according to Claim 23, wherein the shim pseudo-vertebrae is adapted with a longitudinal thickness substantially less than that of drum and wedge pseudo-vertebrae.

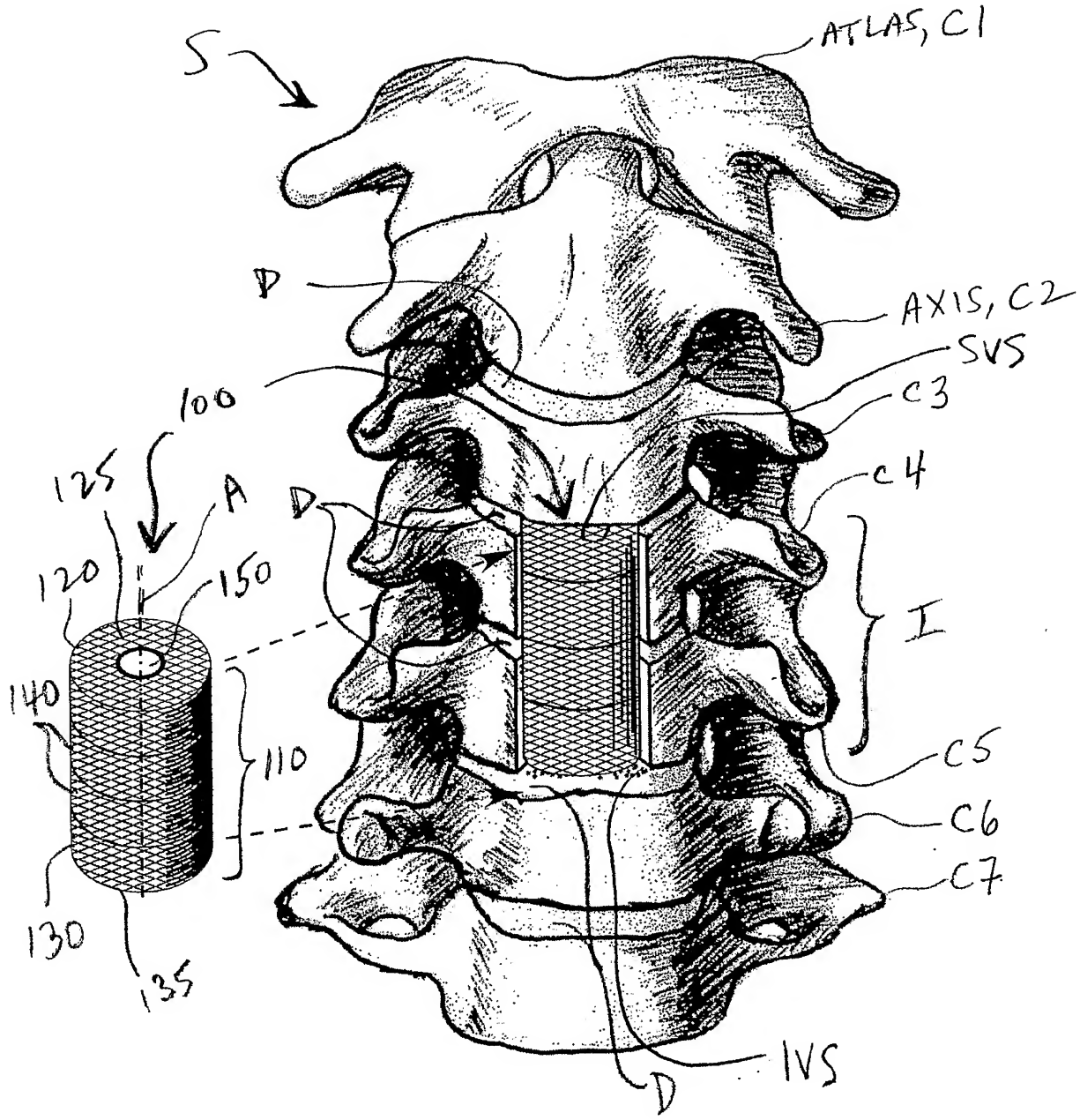
26. The bone graft device according to Claim 23, wherein the at least one wedge pseudo-vertebra is adapted to rotate about an axis substantially parallel with an axis of the at least one stanchion.

27. The bone graft device according to Claim 23, wherein the at least one stanchion is at least partially curved about an axis passing longitudinally therethrough.

28. The bone graft device according to Claim 23, wherein at least two drum pseudo-vertebrae are received about at least two stanchions.

29. The bone graft device according to Claim 23, wherein the at least one stanchion is substantially medially disposed about the plurality of pseudo-vertebrae.

30. The bone graft device according to Claim 23, wherein the at least one stanchion is substantially peripherally disposed about the plurality of pseudo-vertebrae.


S
ATLAS, C1
D
AXIS, C2
SVS
C3
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C4
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A
D
120
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I
140
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C5
C6
C7
130
135
IVS
D

FIG. 1

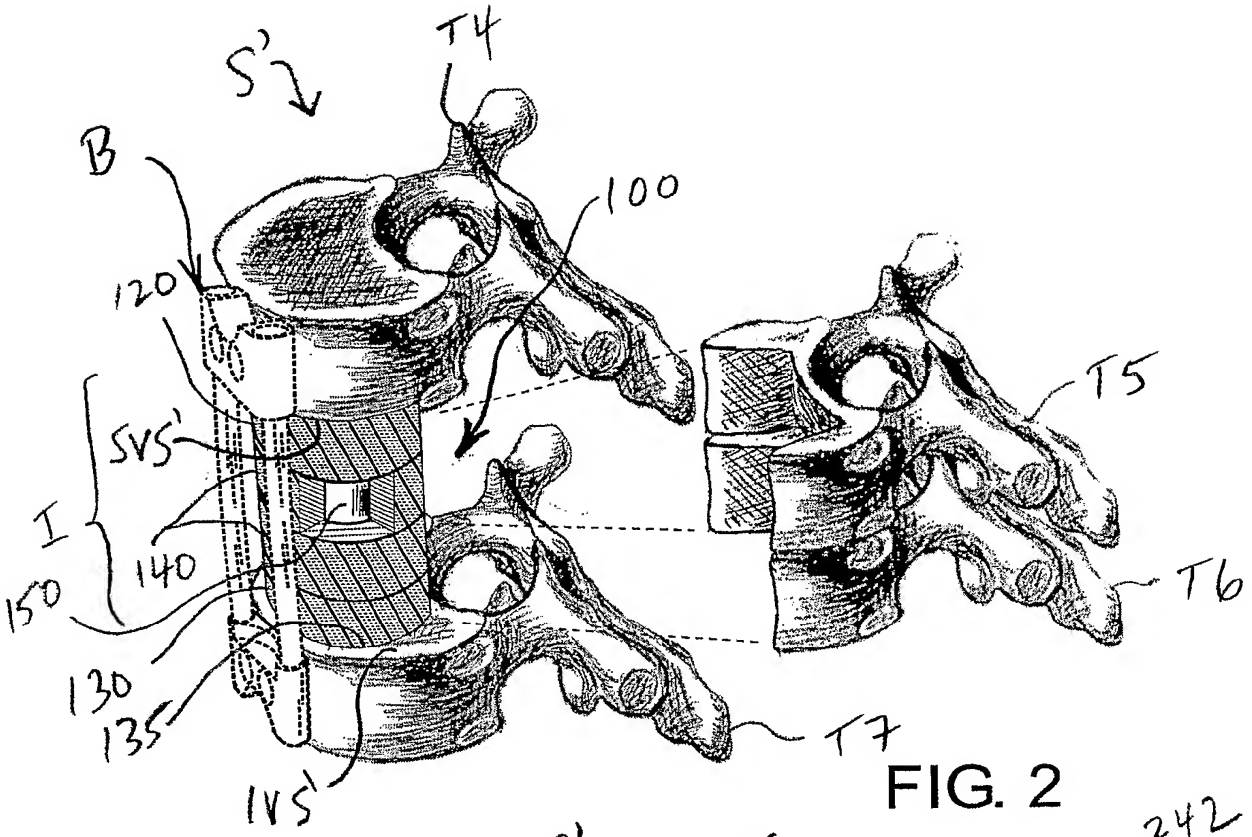

FIG. 2

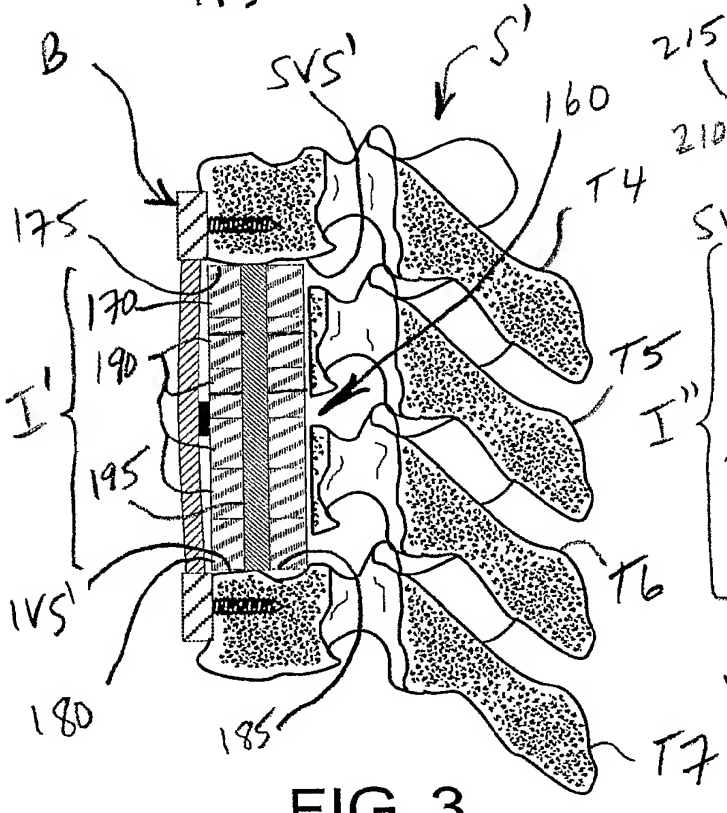

FIG. 3

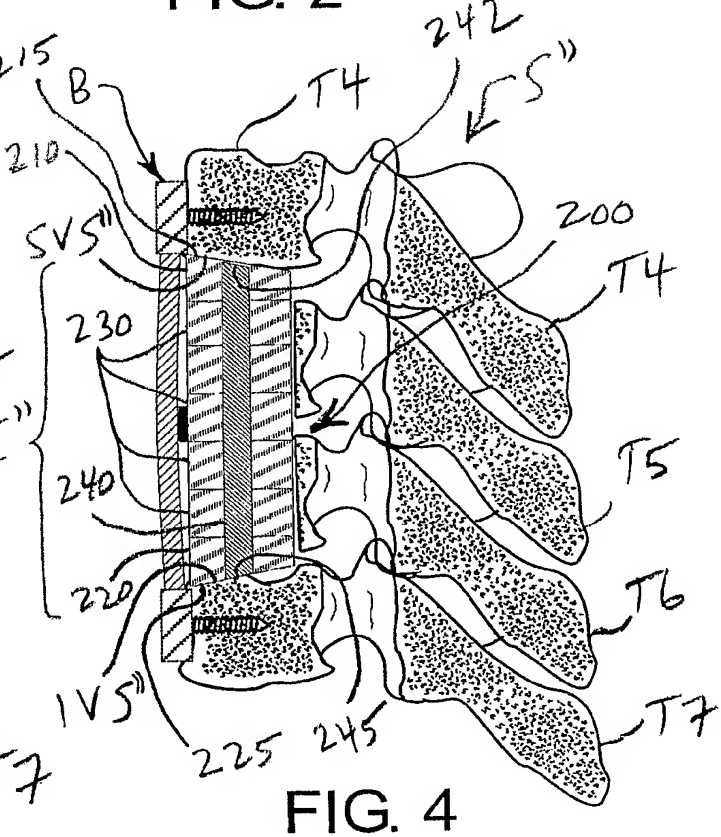

FIG. 4

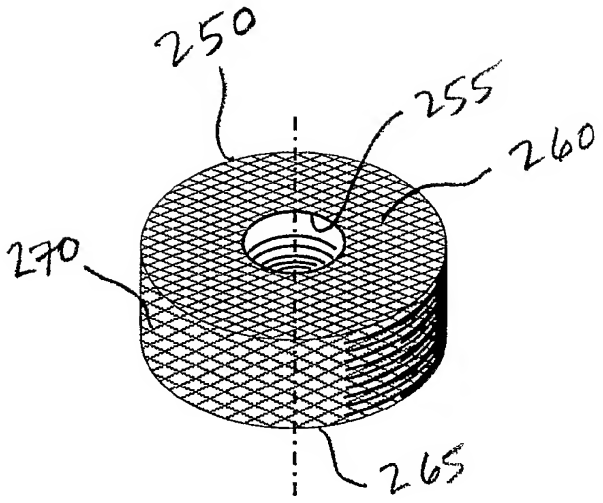

FIG. 5

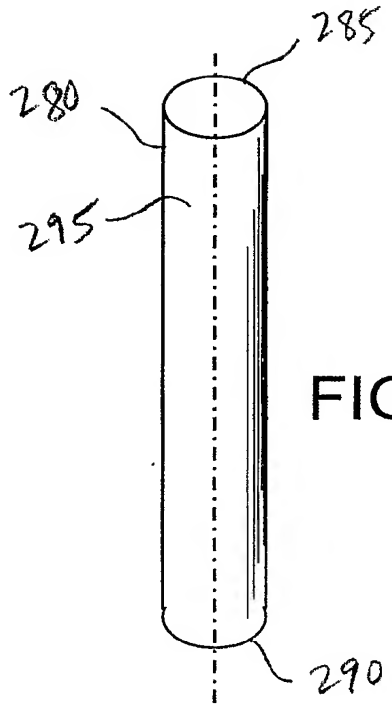

FIG. 6

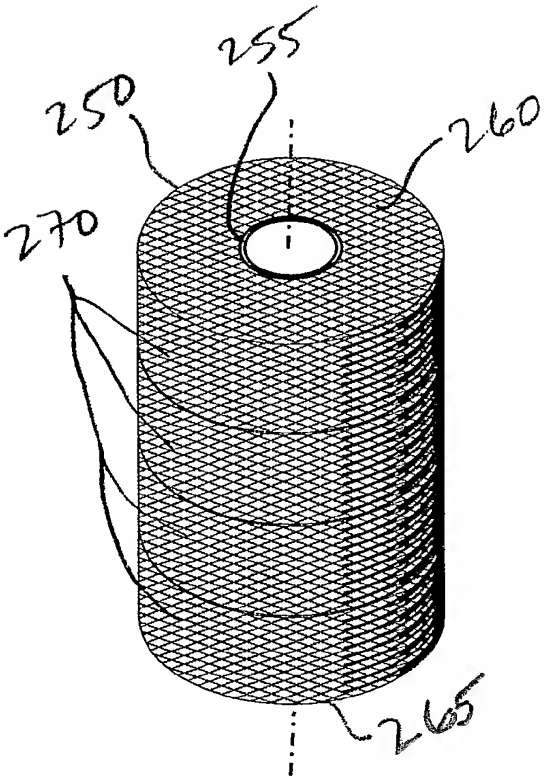

FIG. 7

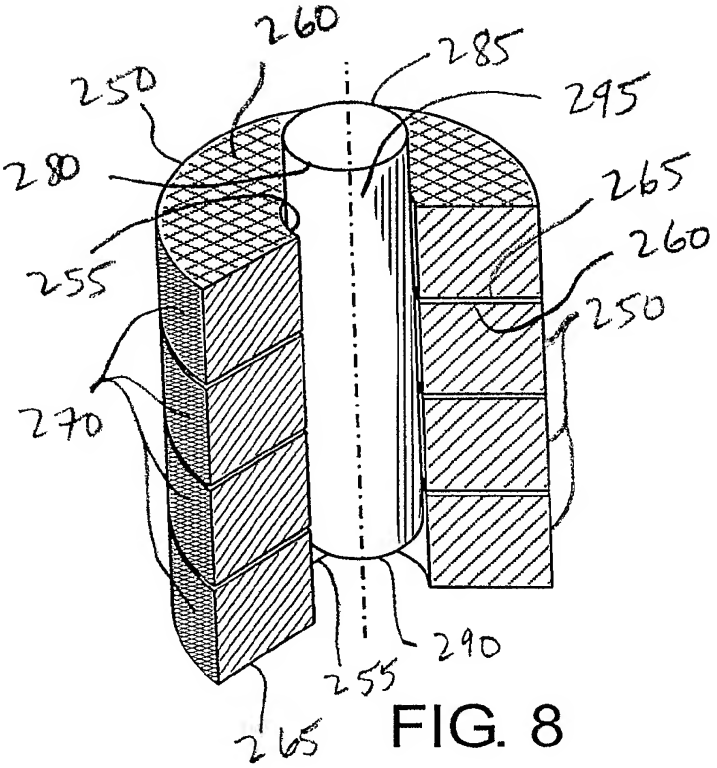

FIG. 8

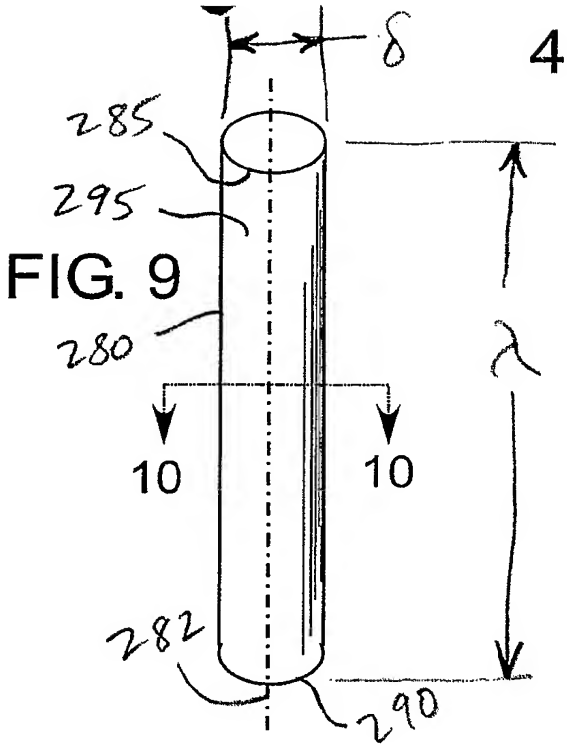

FIG. 9

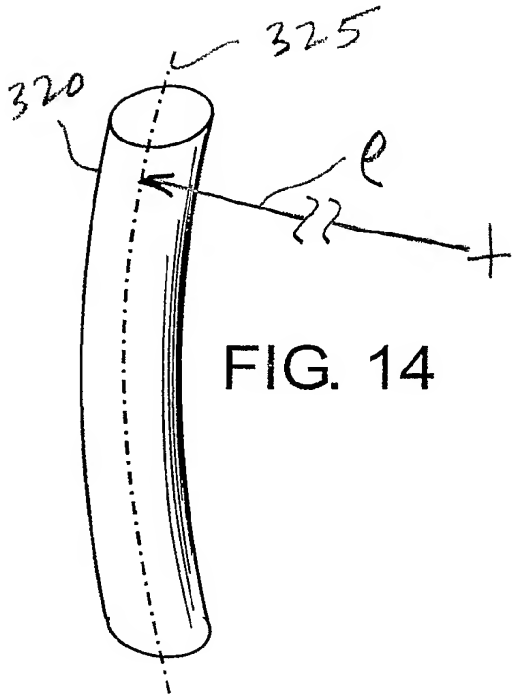

FIG. 14

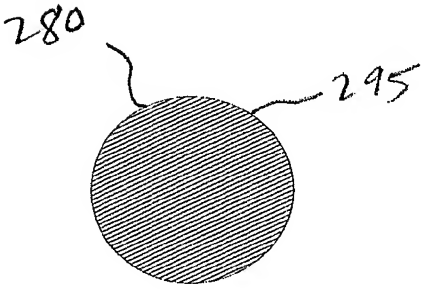

FIG. 10

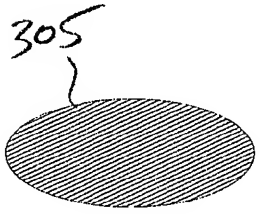

FIG. 12

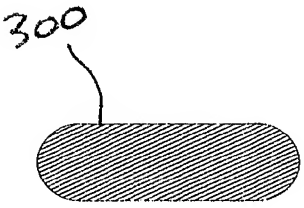

FIG. 11

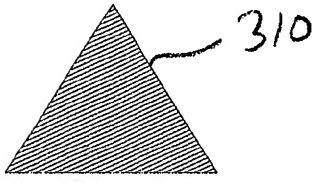

FIG. 13

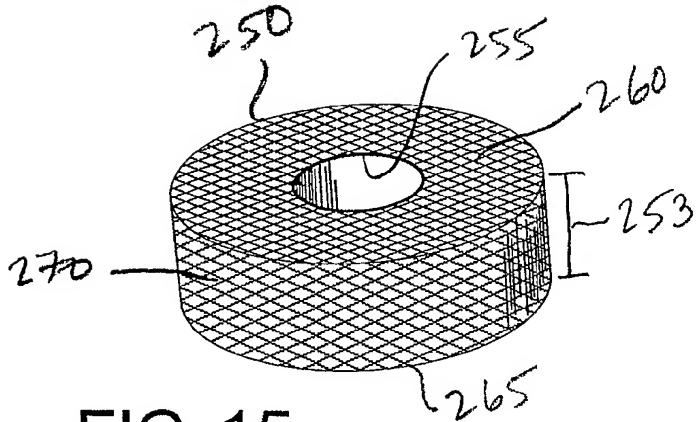

FIG. 15

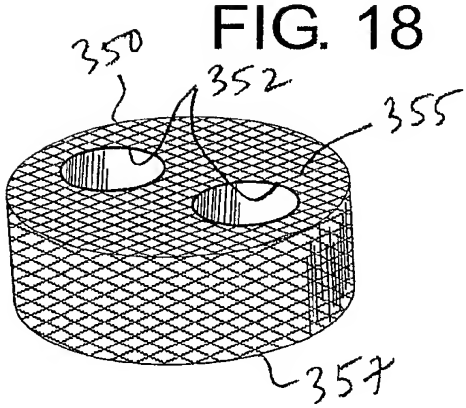

FIG. 18

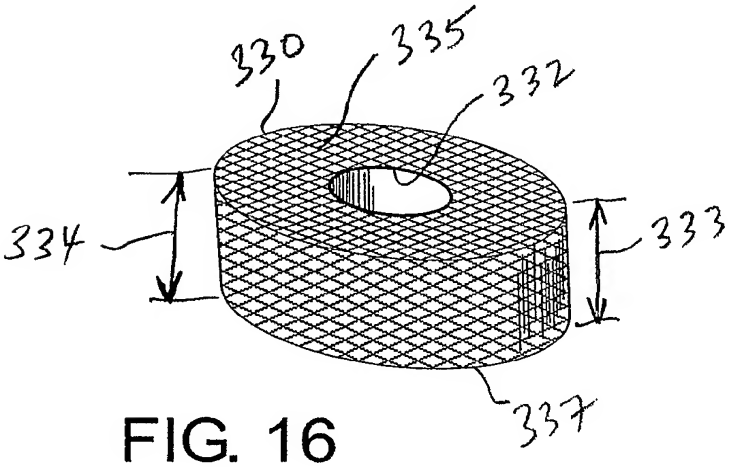

FIG. 16

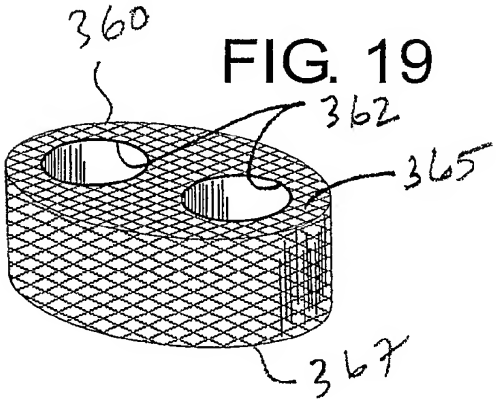

FIG. 19

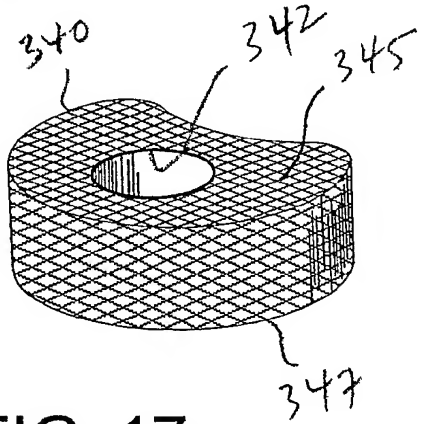

FIG. 17

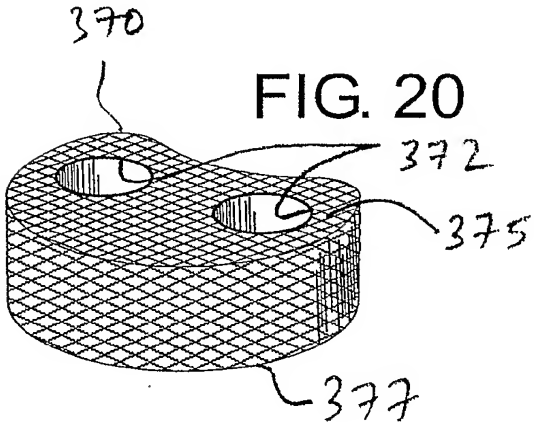

FIG. 20

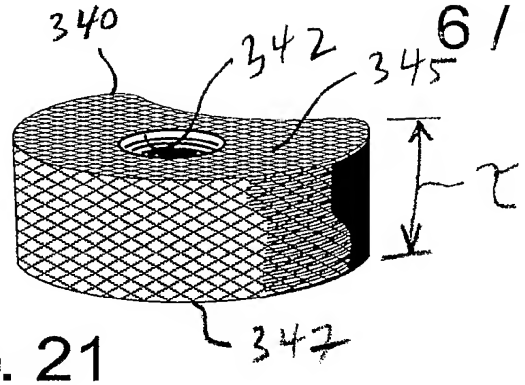

FIG. 21

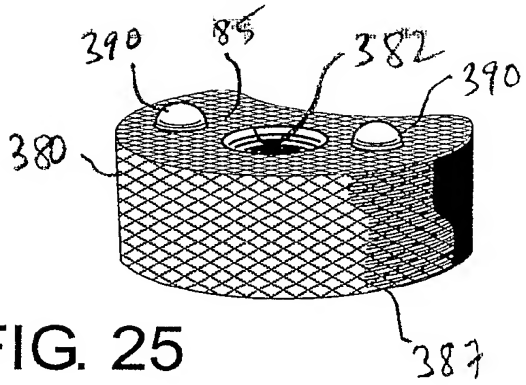

FIG. 25

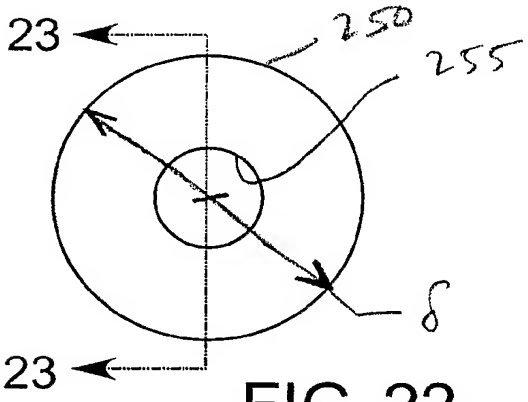

FIG. 22

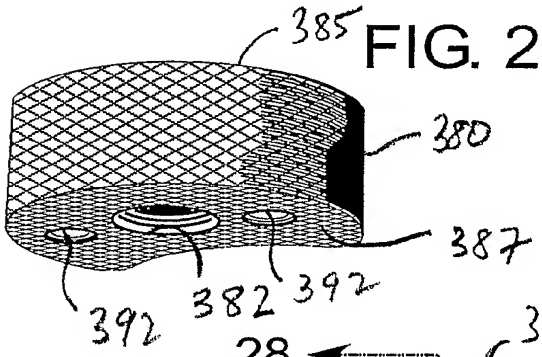

FIG. 26

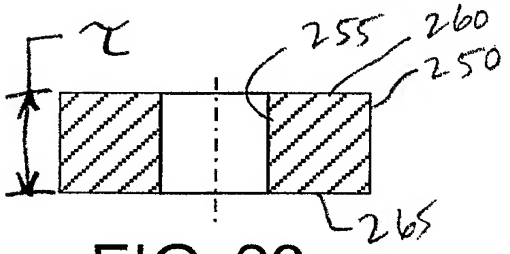

FIG. 23

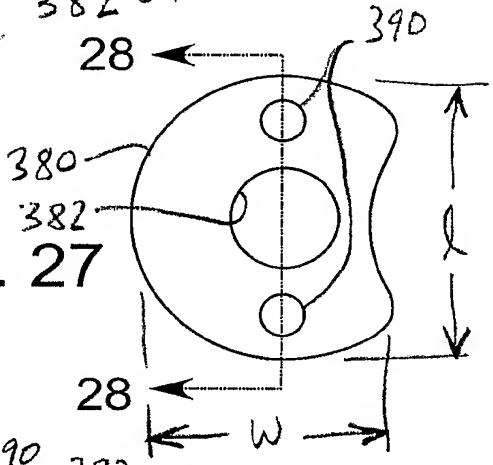

FIG. 27

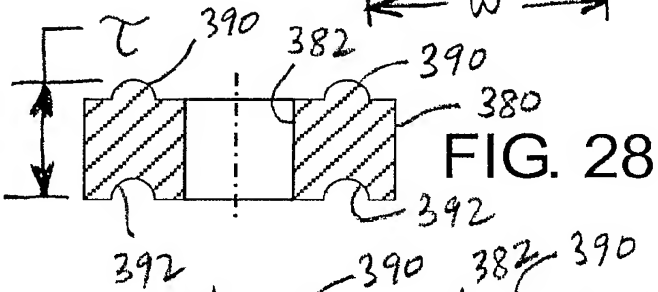

FIG. 28

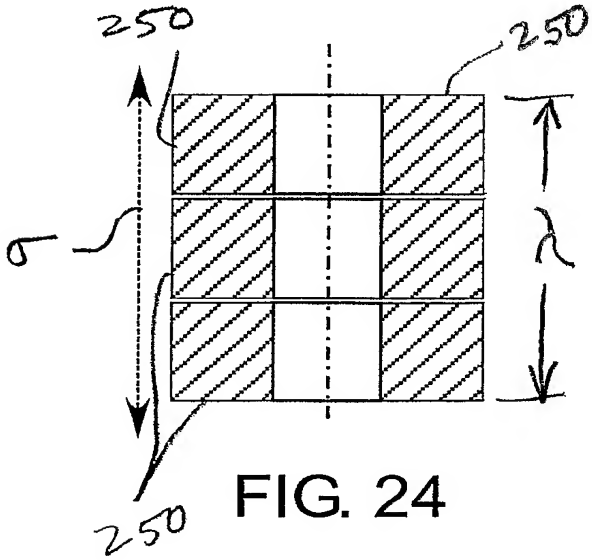

FIG. 24

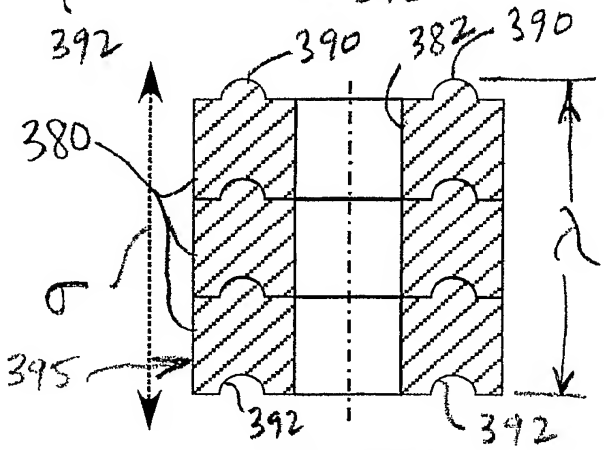

FIG. 29

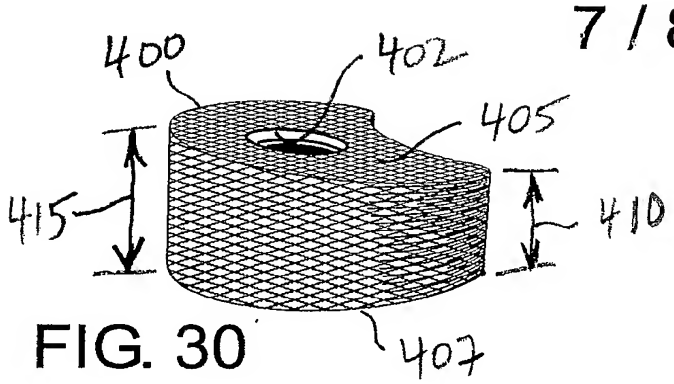

FIG. 30

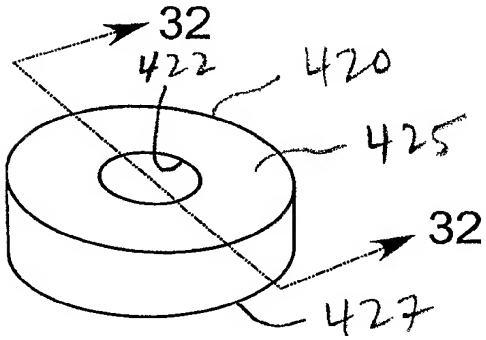

FIG. 31

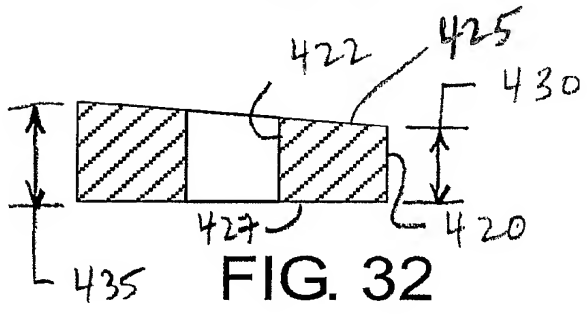

FIG. 32

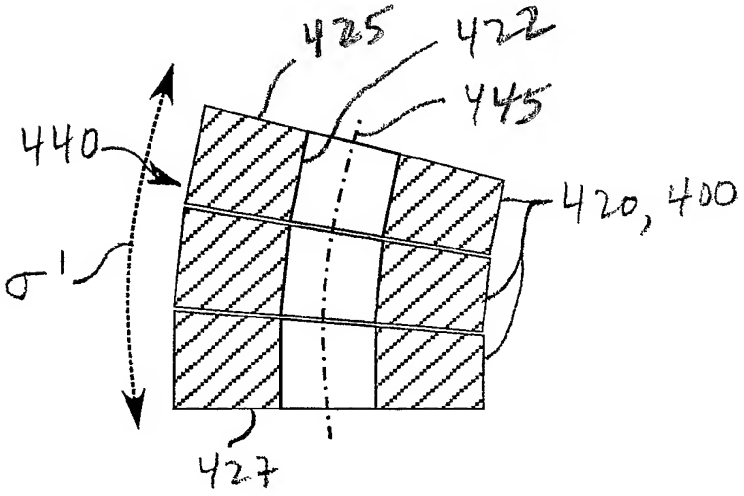

FIG. 33

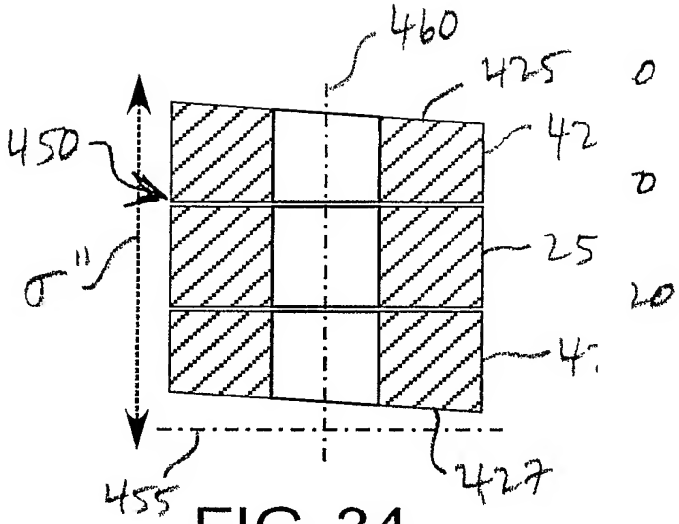

FIG. 34

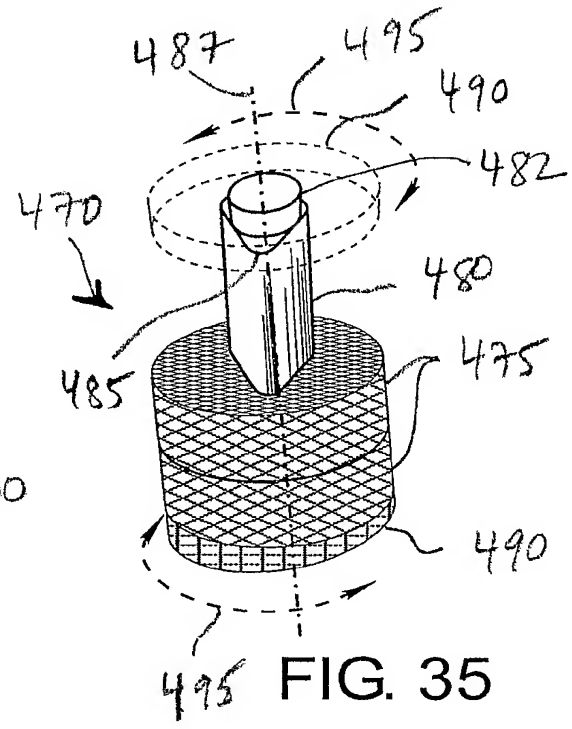

FIG. 35

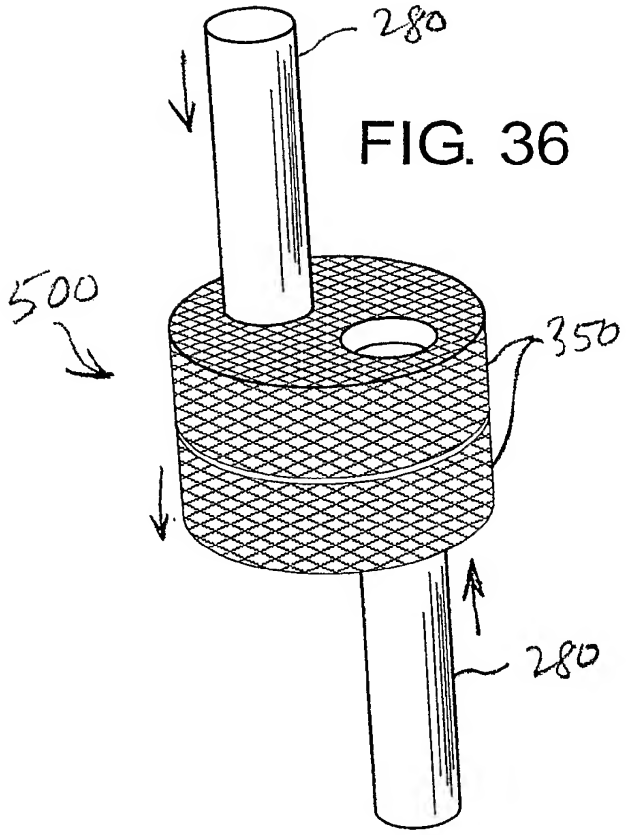

FIG. 36

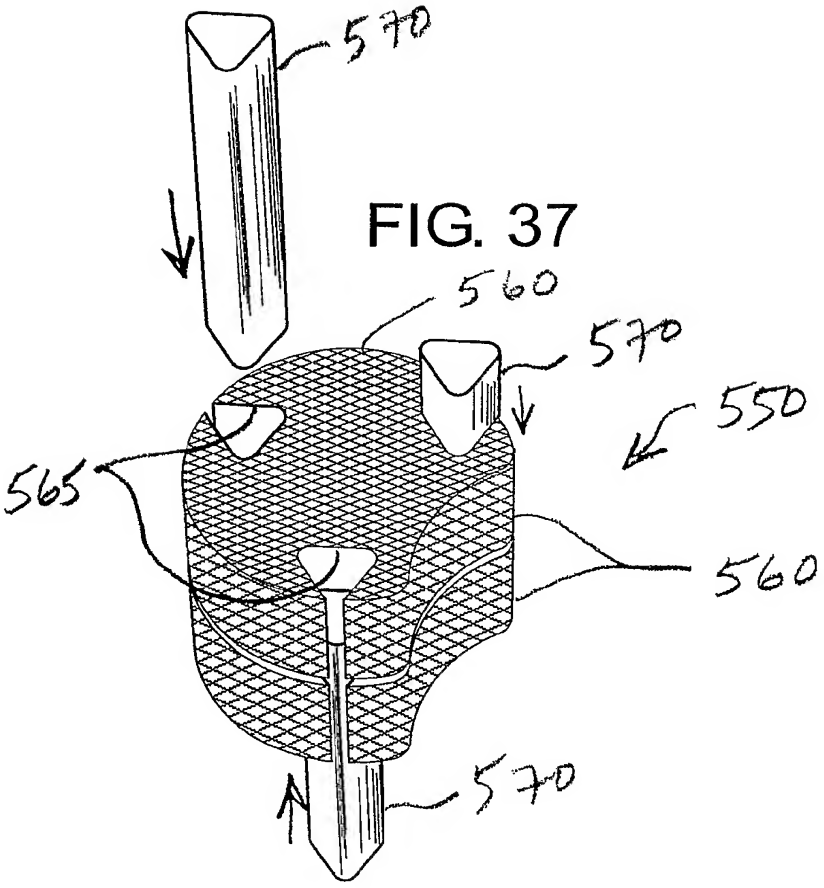

FIG. 37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/28305

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/44
US CL : 623/17.11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/17.11,17.15,17.16

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,192,327 A (Brantigan) 09 March 1993, Figs. 1,3,4,7,9, col. 2, lines 34-38, col. 4, lines 44-49, col. 5, lines 51-55,62-68.	1-6,9,10,23,24,28,29
X,P	US 6,494,883 B1 (Ferree) 17 December 2002, Figs. 7A-7E, 14A, 14B,15A-C, col. 4, lines 46-60, col. 6, lines 32-53.	1-30
X	US 6,106,557 A (Robioneck et al) 22 August 2000, Figs. 2, 9, 17, 18, col. 1, lines 34-37, col. 4, lines 9, 29-35.	1-9,11-17,19-28,30

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

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"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 December 2003 (18.12.2003)	21 JAN 2004
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Brian Pellegrino Telephone No. 703-308-0858

Form PCT/ISA/210 (second sheet) (July 1998)

Continuation of B. FIELDS SEARCHED Item 3:
EAST
text search terms: stackable, rod, support, wedge, vertebrae, rotate